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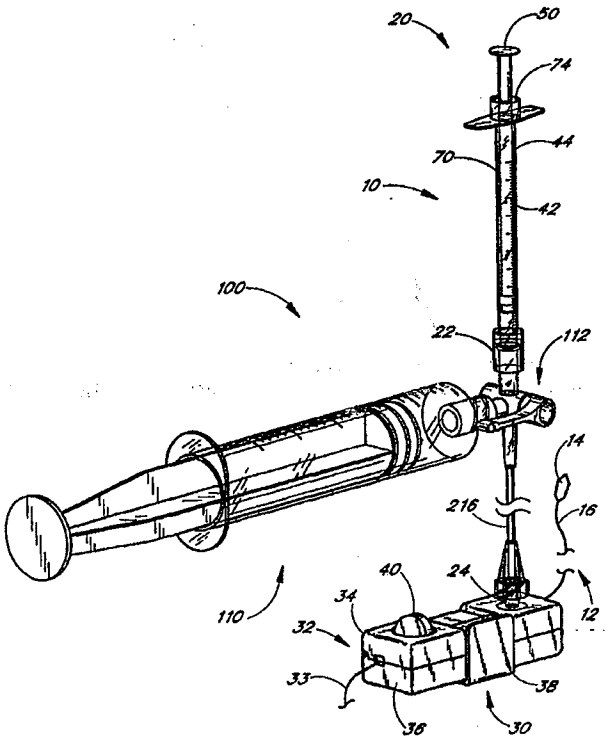
(54) Title: SYRINGE AND METHOD FOR INFLATING LOW VOLUME CATHETER BALLOONS

(57) Abstract

A low volume syringe provides easy, precise delivery of a small amount of fluid for proper inflation of a low volume surgical balloon to occlude emboli. The syringe includes a stop mechanism which limits both the intake and the explusion of fluid contained in the syringe. An elongated cylindrical body allows a user room for error in measuring the delivery of the volume of fluid. The low volume syringe may be used with a larger capacity syringe and a three–way valve to regulate inflation of the low volume catheter balloon. An inflation adaptor may be used to open and close a catheter valve at the proximal end of the hollow catheter. The reservoir syringe is used in a preferred arrangement for evacuating the balloon, catheter and connector prior to insertion of the balloon catheter into the patient at a desired vascular site, and may also be used for deflation of the balloon prior to removal from the patient.



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SYRINGE AND METHOD FOR INFLATING LOW VOLUME CATHETER BALLOONS

Background of the Invention

Field of the Invention

The present invention relates generally to balloon catheters, and, in particular, to an apparatus and method of properly inflating a low volume balloon in a convenient and precise manner without balloon rupture or damage to healthy tissue.

Description of the Related Art

Surgical balloons are used for procedures such as percutaneous transluminal angioplasty for treatment of stenosis, and are also used for occluding blood vessels to prevent release of emboli into the bloodstream during such procedures. A guidewire is conventionally used to guide the insertion of the necessary medical instrument, such as a balloon catheter, to the desired treatment site within a patient's vasculature. A hollow guidewire or guidewire catheter may be used which has a balloon at its distal tip for anchoring the guidewire at the treatment site. An occlusion balloon catheter for emboli containment may have multiple lumens and a pair of occlusion balloons. Alternatively, the balloon on the guidewire or catheter may be used for the occlusion of the vessel downstream of the treatment site.

Occlusion balloons are typically made of compliant material and increase in diameter with increasing inflation pressure until the balloon burst pressure is reached. Occlusion balloons, and balloons used for anchoring guidewires, must be expanded to contact the blood vessel wall. Often, however, the clinician does not know exactly when the balloon has contacted the blood vessel walls or whether uniform circumferential occlusion has been accomplished. In addition, some balloons may undergo longitudinal expansion, further resulting in balloon inflation in a manner that is unpredictable and undesirable with respect to the possible forces on the surrounding healthy tissue.

The inflation of the balloon is conventionally performed using a syringe coupled to the proximal end of the catheter, external to the patient, and having, for example, a fluid capacity of anywhere from 1 cc to 10 cc. The clinician must display patience and concentration in accurately delivering a suitable volume of fluid, such as 0.05 cc, that is required without overinflating the balloon. Although a pressure gauge may be provided on some syringes, the skill required to avoid overinflation is still beyond many clinicians, since a very small movement of the syringe results in a relatively large injection of fluid. That is, unlike therapeutic balloons (which require about 20 atmospheres (atm) pressure and can use syringes ranging between about 10 to 20 cc in fluid capacity), typical occlusion balloons require less than about 3 atm pressure and require only about less than 1 cc. Thus, for delivery of about 0.1 cc fluid using a 10 cc syringe, the travel of the syringe piston is less than about 0.7 mm. It can be readily seen that the control of the piston to this degree of precision would be very difficult. Furthermore, the risks of imprecision are substantial.

Overinflation of the occlusion balloon may cause it to rupture, releasing inflation media into the bloodstream (e.g., fluid, air, gas, etc.), and possibly allowing pieces of the balloon to enter the bloodstream. In addition, the balloon will fail to occlude emboli or anchor the guidewire. Overinflation of the balloon even short of rupture can also cause damage to the healthy tissue adjacent the vessel segment undergoing treatment. The radial expansion

of the balloon can cause undesirable pressure on the vessel wall, and longitudinal expansion of the balloon can cause shearing force which could lead to vessel trauma.

Thus, there is a need for an improved syringe to provide accurate inflation of a low volume surgical balloon without requiring excessive skill.

In addition to the problem of overinflation, another problem exists when inflating the balloons. As discussed above, even though the pressure required to inflate the occlusion balloon is 1 atm the pressure caused by the inflation syringe causes an immediate build up of pressure near the syringe. The build up pressure can reach magnitudes of 200 psi. The build up pressure, however, only lasts for the period of time required to overcome the initial resistance of inflation of the occlusion balloon and then dissipates over the length of the catheter and into the inflated occlusion balloon.

Thus, there is a need for an improved syringe inflation system that can withstand the build up pressure caused by the syringe during the inflation process.

It is also common to use the syringe as a vacuum source either during, aspiration, to remove debris, or in the preparation stage, to remove air bubbles from within the system. The vacuum is typically created by pulling the plunger toward the rear end of the syringe and holding it in place thereby creating a negative pressure in the conduit connected to the plunger. The plunger is typically equipped with an internal ring surrounding the inside of the elongated cylinder of the syringe housing. Once the end of the plunger is pulled over the internal ring the plunger will be locked in place.

Pulling the plunger out to a position near the end of the proximal end of the syringe housing, however, creates a risk of the plunger being pulled out of the housing completely causing a loss of the vacuum and the potential entry of contaminants into the system.

Thus, a need therefore exists to create a syringe, or syringe system, that minimizes the risk of losing the vacuum and contaminating the system.

Summary of the Invention

A syringe and method are provided for easily and precisely inflating medical or surgical balloons requiring minimal amounts of fluid for proper contact with a wall of a cavity in a human body, such as a vessel wall. The syringe is provided with a stop mechanism to provide accurate inflation and prevent overinflation. The syringe may be used alone or coupled, for example, via a three-way valve with a reservoir syringe for delivery of the inflation fluid. A preferred embodiment is illustrated in connection with a guidewire catheter having an occlusion balloon attached; although, the apparatus and method of the present invention are readily adapted for use with other medical balloon devices requiring small inflation volumes to prevent balloon rupture or damage to the surrounding tissue. In addition, the apparatus and method may also be used with somewhat larger, therapeutic balloons, such as for angioplasty procedures, where the enhanced controllability of the inflation fluid delivery which is afforded by the present invention may also be of benefit. The present invention also provides important benefits for non-angioplasty balloon procedures, as well as certain non-balloon applications where medical inflation/injection and/or deflation/evacuation are utilized.

In one aspect of the invention, an inflation or low volume syringe is provided for inflating a medical or surgical balloon attached at a distal end of an elongated tube (e.g., a catheter or cannula) which is inserted into a patient's vasculature. The catheter has a proximal portion, a sealed distal end and an inflation lumen extending therebetween for communicating fluid to the balloon. The syringe comprises an elongated cylinder having a proximal end and a distal end and forming a lumen therebetween. A stop or flange is formed at the proximal end, extending radially away from the lumen, and the distal end is adapted for attachment to the proximal portion of the catheter. A plunger is inserted into the lumen of the cylinder such that a disk on the proximal end of a shaft of the plunger is positioned proximal the flange of the cylinder. The flange and disk are conventionally used to grip and operate the syringe 10 using the fingers and thumb, respectively. The plunger has a resilient piston provided at its distal end which is contained within the lumen of the cylinder.

The syringe advantageously has a stop member provided at the proximal end of the cylinder, with at least a portion of the stop member providing a channel for the plunger shaft to extend therethrough. The stop member has a first segment positioned distal the cylinder flange and a second segment positioned proximal the flange. The stop member limits the travel of the plunger within the cylinder, limiting a maximum volume of fluid that can be drawn into the syringe, and thereby limiting a maximum volume of fluid that can be injected by the syringe.

The second segment may be proximal the plunger disk and a third segment may be provided between the plunger disk and cylinder flange. Preferably, the second segment comprises a barrel provided at the face of the flange and engages the distal face of the plunger disk. Also preferably, the first segment comprises a tube surrounding a portion of the length of the plunger shaft within the cylindrical lumen. In one preferred embodiment, the maximum volumes for intake and injection of fluid by the syringe are different amounts.

The stop member may comprise a separate piece that is retro-fit onto a syringe. Alternatively, the stop member may be integrally formed on the cylinder. The stop member may be fixed with respect to the cylinder flange, or the stop member may be movable with respect to the flange. Preferably, the syringe further comprises an adapter attached at the distal end of the cylinder for connection to a fitting or adapter at the proximal end of the catheter.

A syringe assembly of the present invention combines the low volume syringe as described above with a high volume syringe. The high volume syringe provides the capability to quickly prepare the balloon and catheter lumen prior to insertion into a patient and during deflation of the balloon. That is, the high volume syringe has the power to draw out any air or fluid in the pathway to the balloon, which is deflated prior to use. Preferably, the high volume syringe is connected to the low volume syringe by a stopcock or three-way valve which can be operated to allow flow between a) the high volume syringe and the balloon catheter, b) the high volume syringe and the low volume syringe, or c) the low volume syringe and the balloon catheter. Thus, the necessary steps to prepare for and execute the balloon inflation can be accomplished by the appropriate positioning of the valve.

A method of the present invention includes the filling of the low volume syringe to a limit defined by the stop member provided on the syringe, and the injection of inflation fluid by the syringe to a limit defined by the stop member. In another method of inflating a balloon catheter, a reservoir syringe is attached along with the end of the

catheter and the low volume syringe to the three-way valve. The various settings of the valve allow the reservoir syringe to be used, for example, to evacuate the catheter prior to the procedure, as well as for quick deflation of the balloon for removal from the patient after the procedure.

The syringe or syringe assembly of the present invention may be used with an inflation adapter and low profile catheter valve attached to the proximal end of the balloon catheter, at a side-access inflation port. In this configuration, the catheter valve is used to open and close the side-access inflation port for communicating fluid from the low volume syringe to the inflation lumen of the balloon catheter, and for evacuation/deflation by the reservoir syringe. However, other configurations and/or devices may be used in connection with the present invention in order to gain access to the inflation lumen of the balloon catheter, or, in other words, to allow fluid communication between the present inflation syringe and the medical balloon.

A syringe constructed in accordance with this invention is also useful for multiple lumen emboli containment catheters having multiple medical balloons, not just a single balloon. Further, other balloon procedures, such as is used in ablation, gynecological and urological treatments, may reap the benefits afforded by the syringe and method of the present invention. Moreover, other non-balloon applications, such as irrigation/aspiration, drug delivery, transfusion of whole blood, etc., exist for the syringe and syringe assembly of the present invention.

Thus, in accordance with one embodiment of the present invention, there is provided a syringe adapted for use in medical procedures requiring relatively accurate volumetric delivery of fluids, the syringe comprising an elongate housing having a predetermined cross-sectional dimension and a distal end and a proximal end; and a plunger longitudinally slidable within the housing to effect intake and outflow of the fluids. The plunger has a distal end and a proximal end. The housing is dimensioned such that the cross-sectional dimension has a relatively low profile. The plunger is cooperatively dimensioned within the housing such that a relatively long distance of travel of the plunger within the housing will result in a relatively low volume of fluid intake or outflow, whereby the amount of fluid delivered in the medical procedure can be accurately controlled by tactile manipulation.

The present invention can further be embodied in terms of a syringe adapted for use in medical procedures requiring relatively accurate volumetric delivery of fluids. The syringe comprises an elongated housing and a plunger longitudinally slidable within the housing to effect fluid intake and outflow. A stop mechanism is mounted on the plunger to limit the distance of travel of the plunger within the housing, thereby limiting the intake of fluid. The syringe of the present invention can also comprise an elongated cylinder having a proximal end and a distal end and a lumen extending therebetween with a flange formed at the proximal end and extending radially away from the lumen. The distal end is adapted for attachment to the proximal portion of the tube. A plunger for use in the cylinder and having a shaft with a disk provided at a proximal end and a sealing piston is provided at a distal end of the shaft. The plunger is inserted into the lumen of the cylinder such that the disk is positioned proximal to the flange and a stop mechanism is provided at the proximal end of the cylinder for limiting the intake of the syringe. At least a portion of the stop mechanism provides a channel for the shaft of the plunger to extend therethrough. The stop mechanism has a first segment positioned distal of the flange of the cylinder and a second segment positioned proximal of the flange; whereby the stop mechanism limits the travel of the plunger within the cylinder,

thereby limiting a maximum volume of fluid that can be drawn into the syringe and limiting a maximum volume of fluid that can be injected by the syringe.

The syringe of the present invention can also be comprised of a barrel provided proximal of a finger stop at the proximal end of the syringe cylinder. The barrel preferably has a length and a longitudinal channel formed therethrough. The channel preferably has a diameter sized to received the shaft of the plunger. A tube is provided at a proximal end of the lumen. The tube has an outer diameter less than the diameter of the lumen and an inner diameter forming a longitudinal channel. The inner diameter is sized to receive the shaft of the plunger wherein the tube has a length for limiting the proximal travel of the plunger and thereby limiting a maximum volume of fluid that can be contained in the syringe.

The present invention also comprises a syringe assembly adapted for use in delivering fluids during a medical procedure. The assembly comprises a first syringe; a second syringe; and a fluid conduit for delivering the fluid during the medical procedure. The first syringe is in fluid communication with the second syringe or the fluid conduit. The second syringe is in fluid communication with the first syringe or the fluid conduit. The syringe assembly of the present invention can also comprise a connector having two upstream ports, one downstream port and a flow deflector. The downstream port is configured for attachment to the proximal portion of the tube. A low volume syringe with an elongated body and a stop member is limited to delivery of a relatively small volume of fluid. One of the upstream ports is attached to a distal end of the low volume syringe. A large volume syringe has a relatively large fluid capacity with a distal end of the reservoir syringe adapted to attach to the other of the upstream ports wherein the large volume reservoir syringe is configured to facilitate quick evacuation of the inflation lumen and the balloon. The large volume syringe also provides fluid to the low volume syringe as required.

The present invention may also comprise a method of easily and precisely inflating a low volume balloon catheter comprising the steps of: inserting and positioning a tube and balloon at a desired position within a blood vessel of a patient; providing a three-way valve having first and second inlet ports and an outlet port, where the outlet port is adapted to be attached to the proximal portion of the tube; providing a low volume syringe adapted to be attached to the first inlet port of the valve, where the low volume syringe has an inflation lumen and a stop member for limiting injection of inflation fluid to a predetermined amount; providing a high volume syringe adapted to be attached to the second inlet port of the valve, where the high volume syringe has a reservoir lumen; positioning the valve to communicate the high volume syringe with the lumen of the tube and pulling on a plunger of the high volume syringe to effect evacuation of air or fluid within the tube, the balloon and the outlet port of the connector into the high volume syringe; positioning the valve so that the inflation lumen of the low volume syringe communicates with the lumen of the tube; and pushing the plunger of said low volume syringe to deliver the predetermined amount of fluid to the tube and the balloon whereby the predetermined amount of fluid inflates the balloon to an appropriate size without rupture of the balloon or damage to the blood vessel of the patient.

Another aspect of the invention comprises a method of easily and precisely inflating a low volume balloon catheter comprising an elongated tube having a proximal portion and a sealed distal end with a surgical balloon attached thereto. The tube has a longitudinally extending lumen communicating with the balloon for inflation thereof.

The method comprises the following steps: providing a three-way valve having first and second inlet ports and an outlet port; providing an inflation adapter assembly attached to the outlet port of the three-way valve and attached to the proximal portion of the tube selectively positioned in a first position to allow fluid communication through the inflation adapter and a second position to prevent fluid communication to the inflation adapter; providing a low volume syringe adapted to be attached to the first inlet port of the valve, the low volume syringe having an inflation lumen and a stop member for limiting injection of inflation fluid to a predetermined amount; providing a high volume syringe adapted to be attached to the second inlet port of the valve, the high volume syringe having a reservoir lumen; positioning the inflation adapter in a first position to allow fluid communication through the inflation adapter and to the tube; positioning the valve to communicate the high volume syringe with the lumen of the tube and pulling on a plunger of the high volume syringe to effect evacuation of air or fluid within the tube, the balloon and the outlet port of the connector into the high volume syringe; inserting and positioning the tube and balloon at a desired position within a blood vessel of a patient; positioning the valve so that the inflation lumen of the low volume syringe communicates with the lumen of the tube; positioning the inflation adapter in a first position to allow fluid communication through the inflation adapter and to the tube; pushing the plunger of the low volume syringe to deliver the predetermined amount of fluid to the tube and the balloon; and positioning the inflation adapter in a second position to prevent fluid communication through the inflation adapter and to the tube, whereby the predetermined amount of fluid inflates the balloon to an appropriate size without rupture of the balloon or damage to the blood vessel of the patient.

The present invention also comprises a syringe assembly adapted for use in delivering fluids during a medical procedure, comprising: a low volume syringe; a large volume syringe; a high pressure valve assembly; and a high pressure fluid conduit. The high pressure valve assembly is in fluid communication with the low volume syringe and the large volume syringe and said high pressure line and the high pressure valve selectively allows fluid communication between: the large volume syringe and the low volume syringe, or; the low volume syringe and the high pressure fluid conduit, or; the large volume syringe and the high pressure fluid conduit.

The maximum volume contained in the low volume syringe is in the range of between 0.1 cc to 1 cc of fluid. Preferably, the maximum volume contained in the low volume syringe is in the range of between 0.25 cc to 0.5 cc of fluid. Further, the maximum volume contained in the large volume syringe is in the range of between 10 cc to 30 cc. The high pressure line is preferably rated for use at a pressure of 500 psi and even more preferably the high pressure line is rated for use at a pressure of 250 psi. The high pressure valve of this embodiment is rated for use at a pressure of 750 psi. Even more preferably, the high pressure valve is rated for use at a pressure of 500 psi.

This embodiment of the syringe assembly may also include a syringe stopper element positioned on a proximal end of the large volume syringe to prevent the withdrawal of a plunger reciprocating within a cylinder defining a lumen of the large volume syringe. The syringe stopper element can be integrally molded into a proximal end of the large volume syringe. In an alternative arrangement, the syringe stopper element includes at least two snap fit members removably attached to a proximal end of the large volume syringe.

Yet another embodiment of the present invention is a syringe assembly adapted for use in delivering fluids during a medical procedure, comprising: a low volume syringe; a large volume syringe; a high pressure valve assembly; a high pressure fluid conduit; and a stopper means attached to the large volume syringe for preventing the withdrawal of a plunger reciprocating therein wherein the high pressure valve assembly is in fluid communication with the low volume syringe, the large volume syringe and the high pressure line. The high pressure valve selectively allows fluid communication between: the large volume syringe and the low volume syringe, or; the low volume syringe and the high pressure fluid conduit, or; the large volume syringe and the high pressure fluid conduit.

Yet another embodiment of the present invention is a syringe adapted for use in medical procedures requiring relatively accurate volumetric delivery of fluids, and capable of withstanding relatively high pressures comprising: an elongate housing including a proximal and distal end; a plunger longitudinally slidable within the housing to effect fluid intake and outflow and a coupling for connection to a medical device rated to withstand a pressure of 500 psi.

Another aspect of the present invention is a stop mechanism for a syringe including an elongate housing having a predetermined cross-sectional dimension a distal end and a proximal end, a pair of finger stops extending radially outward from the center of the housing located on a proximal end of the housing, a plunger longitudinally slidable within the housing to effect intake and outflow of the fluids. The plunger including a disk mounted obliquely to the distal end of the plunger. The stop mechanism comprising: at least one stop member removably attached to the finger stop of the elongate housing. The stop member including a stopping surface wherein the stopping surface extends radially inward thereby at least partially closing the distal end of the housing. The stop member preferably is either integrally formed with the finger stop or removably attached to the finger stop or housing.

Yet another aspect of the invention is a method of easily and precisely delivering fluids during a medical procedure through an elongated tube having a proximal portion and a distal end. The tube has a longitudinally extending lumen communicating with the distal end. The method comprises the steps of: inserting and positioning the tube at a desired position within a blood vessel of a patient; providing a three-way valve having first and second inlet ports and an outlet port, the outlet port adapted to be attached to the proximal portion of the tube; providing a low volume syringe adapted to be attached to the first inlet port of the valve, the low volume syringe has an inflation lumen and a stop member for limiting injection of inflation fluid to a predetermined amount; providing a high volume syringe adapted to be attached to the second inlet port of the valve, the high volume syringe having a reservoir lumen; positioning the valve to communicate the high volume syringe with the lumen of the tube and pulling on a plunger of the high volume syringe to effect evacuation of air or fluid within the tube, the balloon and the outlet port of the connector into the high volume syringe; positioning the valve so that the inflation lumen of the low volume syringe communicates with the lumen of the tube; and pushing the plunger of the low volume syringe to deliver the predetermined amount of fluid to the tube and the balloon, whereby the predetermined amount of fluid is delivered to the blood vessel without damage to the blood vessel of the patient.

Preferably the fluid to be delivered is: irrigation fluid, whole blood or a therapeutic drug.

Further advantages and applications will become apparent to those skilled in the art from the following detailed description of the preferred embodiments and the drawings referenced herein, the invention not being limited to any particular embodiment.

Brief Description of the Drawings

Figure 1 shows a preferred embodiment of a syringe assembly having features in accordance with the present invention and operably coupled to an illustrative inflation adapter at a proximal portion of a balloon catheter;

Figure 2 shows a perspective view of the catheter valve and balloon catheter of Figure 1 placed within an open inflation adapter;

Figures 3A and 3B show the closed and open low profile catheter valve positions, respectively;

Figure 4 shows the syringe assembly of Figure 1 including a low volume syringe and a high volume syringe operably coupled using a three-way valve;

Figures 5A-5C show the various positions of the three-way valve which determine the flow between the syringes and the balloon catheter;

Figure 6 shows a cross-sectional view along the longitudinal axis of the preferred embodiment of the low volume syringe of the present invention;

Figure 6A shows a cross-sectional schematic view of the stop mechanism of the low volume syringe of Figure 6.

Figure 7 shows an end view of the low volume syringe of Figure 6;

Figure 8 shows a syringe having an alternative embodiment of a stop member;

Figures 9A and 9B show a syringe having yet another embodiment of a stop member;

Figures 10 and 11 show alternative connections of a low volume syringe having features in accordance with the present invention;

Figure 12 shows an alternative syringe assembly utilizing the low volume syringe of Figure 6;

Figure 13 shows a preferred embodiment of a high pressure syringe assembly with an exploded view of the plunger stop mechanism;

Figure 14A shows a plan view the plunger stop mechanism of Figure 13; and

Figure 14B shows a cross section of Figure 14A taken along the line 14B-14B.

Detailed Description of the Preferred Embodiments

A preferred embodiment of a low volume or inflation syringe 10 in a syringe assembly 100 having features in accordance with the present invention is shown in **Figure 1**. Also shown in **Figure 1** is an illustrative connection of the assembly 100 to an occlusion balloon guidewire catheter 12 utilizing an inflation adapter 30. The syringe assembly 100, comprising the inflation syringe 10 and a larger capacity or reservoir syringe 110, is attached via tubing 216 to the inflation adapter 30 within which a low profile catheter valve 32 and the balloon catheter 12 are engaged during use.

The catheter valve 32, described in more detail below in connection with **Figures 3A and 3B**, is attached to an open proximal end of the catheter 12. The syringe 10 is used to inject inflation fluid through the adapter 30

and valve 32 into a lumen of the hollow catheter 12, and into the balloon 14. The inflation adapter 30, described in more detail below in connection with **Figure 2**, is used to open and close the valve 32 to regulate the inflation of the balloon 14 mounted on the distal end of the catheter 12. Nevertheless, it will be emphasized that other types of adapters and/or valves can be employed with the inflation syringe and/or syringe assembly of the present inflation, in order to achieve rapid and accurate inflation/deflation of medical balloons or other non-balloon medical devices. Therefore, although the present inflation is illustrated in connection with a low volume occlusion balloon 14, other types of balloons and non-balloon devices can benefit from the advantages of the invention.

The balloon 14 is mounted on a distal end of a hollow guidewire 16 which defines the inflation lumen for the balloon 14, and the syringe 10 and/or syringe assembly 100 is connected at the proximal control end 32 of the guidewire 16. Prior to use of the syringe 10 to inflate the balloon 14 to the proper size for the vascular segment to be treated, the guidewire 16 and balloon 14 are first "primed" or evacuated. The reservoir syringe 110 of the assembly 100 may be used for the evacuation. Access to the vascular site is through a port in the patient obtained, for example, using an introducer (not shown). A preferred system and method for accomplishing the occlusion balloon inflation is described below.

Generally, the inflation syringe 10 of the present invention is provided with a stop mechanism 20 for limiting both the intake of fluid into the syringe and the delivery of fluid from the syringe. Various embodiments of such a stop mechanism 20 are described in more detail below in connection with **Figures 6-9**. The syringe 10 has an elongate cylinder 44 and plunger arrangement 50 which provide for greater displacement or travel by the plunger along the cylinder length than is necessary to expel a relatively small amount of inflation fluid. Thus, with the stop mechanism 20, the clinician is provided with an enhanced sense of whether the fluid in the syringe 10 has been delivered to the balloon, which helps compensate for lack of precision by the clinician. The stop mechanism 20 may be mounted on the syringe 10 during production, or as separate components that can be retro-fit onto an existing supply of syringes.

Overview of Balloon Inflation/Deflation

Referring to **Figures 1-3**, a balloon guidewire catheter 12 has a low profile catheter valve 32 attached to a proximal end of the guidewire 16 having a side-access inflation port 17, shown in greater detail in **Figures 3A and 3B**. The inflation port 17, proximal end of the catheter 12 and distal end of the valve 32 is positioned within the inflation adapter 30 (see **Figure 2**) to which a syringe assembly 100 in accordance with the present invention has been operably coupled. The inflation syringe 10 is coupled via an injection cap 22 at its distal end to a valve 112 that also connects the large capacity syringe 110 and a short tube segment 216. The tube segment 216 is adapted to connect to a fitting or male luer member 24 of the inflation adapter 30. Thus, the valve 32 is opened and closed by the adapter 30 to allow use of the low volume syringe 10 of the syringe assembly 100 to inflate the balloon 14 at the end of the catheter 12. It will be apparent especially from **Figures 3A and 3B** that the valve 32 is considered "low profile" since it is no larger in cross-sectional diameter than the catheter 12 itself.

Referring to **Figures 1 and 2**, the inflation adapter 30 comprises a housing having two halves 34, 36 preferably formed of metal, medical grade polycarbonate, or the like. The halves 34, 36 are attached by hinges 205

to be separated or joined in a clam shell manner. A locking clip 38 secures the halves while the adapter 30 is in use. A groove within the housing has a width to accept the proximal end 33 of the catheter 12 having the low profile valve 32. The male luer member 24 (**Figure 1**), or other suitable connector, extends from a top of the housing to provide an inflation passageway. Seals 280 are provided within the housing and around the internal segment 285 of the inflation pathway to conduct the pressurized fluid provided by the syringe 10 attached to the male luer member 24.

In one embodiment shown in **Figures 3A and 3B**, the low profile catheter valve 32 comprises a movable sealer portion 35 attached at a distal end of a wire segment 37 and positioned within an inflation lumen 15 of the guidewire catheter 12. The wire 37 may be secured to a spring just within a proximal opening of the catheter 12. It will be noted that various spring or biasing arrangements may be utilized, including a zig-zag wire 41 which is formed on or replaces the wire segment and which provides biasing force to the sealer portion 35 due to frictional engagement with the walls of the lumen 15. The sealer portion 35 forms a fluid tight seal with the inflation lumen 15 by firmly contacting the entire circumference of a section of the inflation lumen 15. The sealer portion 35 may be positioned proximally of the side-access inflation port 17 on the catheter to establish an unrestricted fluid pathway between the inflation port 17 and the inflatable balloon 14 on the distal end. As desired, the clinician may move the sealer portion to a position at, or distal of, the inflation port, thereby preventing any fluid from being introduced into or withdrawn from the balloon 14 via the inflation port 17.

An actuator 40, shown in **Figure 1** at the top of the adapter housing, controls a cam which operates sliding panels 291 (**Figure 2**) contained in the housing. Preferably, the catheter 12 is positioned within the housing with the valve closed (**Figure 3A**), such that the side inflation port 17 is located in the sealed inflation area 285 of the housing. An adjacent proximal portion of the catheter extends outside the housing (and the patient), and a proximal portion 33 of the catheter valve 32 extends out of the other side of the housing. The locking clip 38 is then secured and then the syringe 10 may be attached. The actuator 40 is moved from a first position to a second position, such that the sliding panels 291 within the housing cause the valve to be in an open position to allow fluid flow through the inflation port 17 (**Figure 3B**). Closing the valve is accomplished by moving the actuator 40 from the second position back to the first position (**Figure 3A**), such that the balloon inflation is maintained.

Other inflation adapters may be used with the inflation syringe of the present invention as desired. Other connectors or fittings, such as tubing, quick connects and Y-connectors, may also be used according to the particular application and available supply of equipment, as shown, for example, in **Figures 10-11.** (In **Figure 10**, for example, the inflation syringe is connected via the injection cap 22 directly to the guidewire 16 to allow inflation of the balloon 14 on the catheter. In **Figure 11**, the inflation syringe 10 is connected via a short tubing 216 to a y-connector 210 which is in turn in fluid communication with the catheter 12. Thus, a variety of inflation devices and techniques are available in connection with the inflation syringe 10 of the present invention.)

Occlusion Balloon Guidewire

The guidewire 16, or catheter used as a guidewire, has an inflation lumen 15 for communicating pressurized inflation fluid, such as a saline solution or contrast dye, to the balloon 14. The lumen 15 extends from the open proximal end to the sealed distal end which has a side opening for communication with the balloon interior.

Preferably, the hollow guidewire material is stainless steel, or, alternatively, an alloy of nickel and titanium known as nitinol. Alternatively, another metallic material such as titanium may be used. Other biocompatible elongate flexible tubes, made of polymeric materials such as nylon, polyamide, polyethylenes, or combinations thereof, for example, are also appropriate for use with the present invention. The guidewire 16 is preferably circular in cross-section with an outer diameter (OD) of about 0.010" (0.0254 cm) to 0.044" (0.11176 cm). More preferably, the OD is no more than about 0.020" (0.0508 cm). The inner diameter (ID) of the guidewire 16, or lumen diameter, is preferably from about 0.008" to 0.010" (0.02032 to 0.0254 cm), and more preferably about 0.009" (0.02286 cm).

The occlusion balloon 14 is preferably made of a block copolymer of styrene-ethylene-butylene-styrene (SEBS) such as C-Flex (TM) available from Consolidated Polymer Technologies. More preferably, the balloon material is C-Flex (TM) resin grade R70-050-000. The balloon 14 is attached to the guidewire 16 using any conventional method, such as heat bonding or adhesives. For example, for attachment of a SEBS balloon to a nitinol tube, a primer such as 7701 LOCTITE (TM) by Loctite Corporation is preferably used along with cyanoacrylate adhesive such as LOCTITE 4011.

Low Volume Syringe

A preferred construction of the low volume syringe 10 is shown schematically in **Figure 6.** The type or size illustrated is a 0.5 cc tuberculin syringe, although other size syringes having capacity ranging between about 0.02 cc to 1.0 cc may be used. More preferably, the capacity of the low volume syringe is between about 0.25 to 0.50 cc. The resultant displacement required for delivery of about 0.1 cc fluid is about 10 mm for a 0.25 cc syringe. Indicia 42 may be provided along the length of the exterior surface of a cylinder 44 for visual aid of the clinician during use. Nevertheless, as described below in more detail, a stop mechanism is advantageously provided on the syringe 10 in order to accurately limit the inflation fluid intake and expulsion, thereby providing a means for the clinician to safely and accurately perform the desired procedure.

Referring to **Figures 6 and 7,** the elongate body of the syringe comprises a cylinder 44 having a stop or flange 46 extending radially outward at a proximal end and preferably being attached at a distal end to an injection cap 22. The distal end of the cylinder 44 has a nose portion 48 with a reduced diameter for connection with the injection cap 22. A plunger 50 has a shaft 52 of appropriate length and a resilient piston 54 attached at its distal end. The shaft 52 is inserted in a central lumen 56 of the cylinder and the piston 54 provides sealing engagement with the inner surface of the cylinder 44. The plunger 50 has a disk 58 at the proximal end of the shaft 52 for operation of the plunger 50. A preferred source for unmodified, conventional syringes is Becton Dickinson & Co. of Franklin Lakes, New Jersey.

The injection cap 22 preferably comprises a modified female member of a luer type connector. A first end 60 of the cap has a proximal wall with an aperture corresponding to the outer diameter of the cylinder 44, and a distal wall having an aperture corresponding to the outer diameter of the nose 48. These apertures are used to

mount the injection cap 22 on the syringe 10. A threaded second end 62 of the cap can be screwed onto a male luer member 24, as in the examples of **Figures 1 and 4.** Alternatively, a tubular segment 64 within the second end 62 of the cap may be directly attached to the control end of the guidewire 16 using a sleeve 66, as described in more detail above in connection with **Figure 10.** Other suitable cap configurations may also be used to facilitate coupling of the syringe to a guidewire or catheter to provide inflation of the balloon. One preferred source of the cap is Medical Disposables International, Inc. of West Conshohocken, Pennsylvania.

Stop Member

In the embodiment of **Figures 6 and 7,** the limiting of the fluid intake and expulsion is accomplished by a tube 70 on the plunger 50 both of which are contained within the lumen 56 of the cylinder 44. The tube 70 has a length shorter than the lengths of the cylinder 44 and the shaft 52 and this length determines the volumetric intake and expulsion of the fluid from the syringe. The inner diameter of the tube 70 is preferably sized to be approximately the same as the outer diameter of the plunger shaft 52. The tube 70 is circumferentially attached to the plunger shaft 52, as shown in **Figure 7.** Preferably, an adhesive, such as LOCTITE (TM) 4011 is used to secure the tube 70 to the shaft 52; although, attachment of the tube 70 to the plunger shaft 52 is not required to achieve the benefits of the present invention.

In use, for intake of the inflation fluid, a proximal end of the tube 70 contacts a distal face 72 of an insert within the barrel 74, as shown in more detail in **Figure 6A,** thus providing a stop mechanism for limiting the intake of inflation fluid (and thereby limiting the amount of fluid which is available for inflation). The barrel 74 is attached to a proximal face 76 of the flange 46 and thereby limits the plunger's outward or proximal travel with respect to the cylinder 44. The barrel 74 has a central channel 78 sized to allow the plunger shaft 52 to slide through, but not the plunger shaft 52 having the tube 70 surrounding it. Preferably, the distal end of the barrel 74 is secured to the face 76 of the flange 46 using adhesive. Alternatively, the tube 70 and barrel 74 may be integrally formed with the plunger 50 and flange 46, respectively, of the syringe 10.

It will be noted from **Figure 6** that the proximal face 73 of the barrel 74 can be positioned a predetermined distance from the disk 58. In other words, the length of the barrel 74 can be varied so that the proximal surface 73 thereof may also serve as a stop mechanism, alone or in combination with action of the tube 70.

For the 0.5 cc syringe shown, preferred dimensions of the tube 70 include an OD of about 0.135" (0.3429 cm) and an ID of about 0.127" (0.32258 cm), with a tube length of about 45 mm. The preferred tube material is nylon 12. The corresponding preferred dimensions of the barrel 74 are an OD of about 0.288" (0.73152 cm) and an ID of about 0.128" (0.32512 cm), with a barrel length of about 0.260" (0.6604 cm). The preferred barrel material is a polycarbonate.

An alternative embodiment of the low volume syringe is shown in **Figure 8,** wherein a conventional syringe 88 is retro-fit with a stop member 80 that is attached over the proximal end of the syringe. The member 80 includes an attachment portion 82 and two limiting portions 84, 86. The attachment portion 82 is at the distal end of the member 80 and may be secured to the distal face 77 of the cylinder flange 46 using adhesive, or it may be attached to the outer surface of the cylinder 44. The limiting portion 86 at the proximal end of the member extends

proximally past the plunger disk 58, or in a direction away from the plunger shaft 52. At least this portion 86 should be limited to two segments of an annular disk of no more than about 45 degrees each, for example, to allow a proximal opening sufficient for a thumb or the like to access the plunger disk 58. The other limiting portion 84, intermediate the other portions 82, 86, is positioned between the cylinder flange 46 and the plunger disk 58. Thus, the limiting portions 84, 86 form the intake and delivery stops for the modified syringe 88; although, in alternative embodiments, the portion 84 may be omitted without loss of benefit of the present invention.

Another embodiment of a retro-fit stop member 90 for a conventional syringe is shown in **Figures 9A and 9B**. A preferably C-shaped attachment disk 92 has an arm 94 extending transverse to its diameter and parallel to the length of the syringe cylinder 44. A smaller disk 96 is provided at right angles to the arm 94 and is substantially parallel to and aligned over the C-shaped disk 92. The opening of the C-shaped disk 92 allows the member 90 to be snapped into place over the distal end of the syringe cylinder 44 and is preferably left free to slide thereover. The smaller disk 96 is preferably glued to the outer face of the plunger disk 58. Alternatively, the C-shaped disk 92 could be glued into place on the cylinder 44, and the smaller disk 96 could be left free to engage and disengage the plunger disk 58 during use. Thus, the intake or travel of the plunger 50 in this modified syringe is limited by the length of the arm 94 of the stop member 90.

Another arm (not shown) comprising a member extending parallel to the C-shaped disk 92 and smaller disk 96 and provided along the longitudinal arm 94 between the two disks 92, 96 may be provided to limit the amount delivered by the syringe, in a manner similar to **Figure 8**. Although, if the predetermined amount of fluid to be drawn into the inflation syringe is to be the same as the predetermined amount of fluid to be delivered or injected by the syringe, then the construction shown in **Figures 9A and 9B** accomplishes this goal.

The stop member 20, 80, 90 is preferably made of a resilient material and manufactured in various lengths. The member may be integrally formed, as a retro-fit mechanism or directly on the syringe, or assembled from smaller components. As a retro-fit, the stop member may have alternative configurations that can be hinged, snapped or clipped into place, for example, over the proximal end of the syringe. The retro-fitting is also suitable for providing advantages of the low volume syringe of the present invention to syringes comprising larger diameter plunger barrels that preclude the use of a tube 70 in the cylinder lumen 56.

Inflation Syringe Assembly

In the embodiment of **Figure 4**, the inflation syringe 10 is used in an assembly 100 including a conventional high capacity or reservoir syringe 110, coupled therewith by a connector or valve 112. The reservoir syringe 110 provides the desirable power and volume for quickly priming the balloon 14, guidewire 16 and valve 112, as well as for quickly deflating the balloon 14 for withdrawal from the patient. However, it will be noted that the inflation syringe 10 can be utilized in combination with other reservoir systems, of which the assembly 100 is only one example.

Thus, in the embodiment of **Figure 4**, a syringe assembly 100 is shown attached to a proximal end of a short tube section 216 using a stopcock or three-way valve 112. The tube section 216 is in turn attached to the fitting 24 of the inflation adapter 30, as shown in **Figure 1**. Alternatively, as discussed below in more detail, the

syringe assembly 100 may be directly coupled, without the adapter 30, to the proximal end of the guidewire catheter 12 using the valve 112.

The assembly 100 is operably coupled using the valve 112 to allow fluid to flow in one of three paths provided by lumens in three fittings 114, 116, 118 of the valve 112. **Figures 5A-5C** show various positions of the valve 112 during operation and are described in detail below. It is understood that other valves may be used for allowing directional control of the inflation fluid. Thus, referring again to **Figure 4**, the end of the tube 216 is attached to one of the fittings 114, a large capacity or reservoir syringe 110 is attached at a second fitting 116, and a low volume or inflation syringe 10 constructed in accordance with the present invention is attached to the third fitting 118. The reservoir syringe 110 is any conventional type having a capacity of between about 10-30 cc, for example. In the example shown, the inflation syringe 10 of **Figure 6** is used; although, it is readily apparent that any other syringe having a stop member constructed in accordance with the present invention may also be used.

The end of the tube section 216 is preferably attached to the valve fitting 114 using a sleeve 120. The remaining two valve fittings 116, 118 preferably comprise male luers, and a distal end of the reservoir syringe 110 is preferably threaded for engagement to one fitting 116. The distal end 62 of the injection cap 22 is also threadably engaged with the remaining valve fitting 118. Although the reservoir syringe 110 is shown attached to the intermediate fitting 116, the inflation syringe 10 could alternatively be attached at that location with the reservoir syringe 110 attached at the side fitting 118 of the valve 112.

As noted above, **Figures 5A-5C** illustrate the operation, various schematic side views, of the valve 112 which is utilized in connection with the syringe assembly 100 of the present invention. These figures illustrate the valve 112 in partial cross-section with the reservoir syringe 110 removed such that its position would be coming out of the page toward the reader, as illustrated in the top view of **Figure 4**. Likewise, the inflation syringe 10 and its connection via injection cap 22 are shown to the left and the short tubing 216 leading to the inflation lumen 15 of the balloon catheter 14 is illustrated leading to the right, in a manner consistent with **Figure 4**.

Referring in detail to **Figure 5A**, a central member 122 of the valve 112 is operated to allow flow between the inflation lumen 15 of the guidewire 16 (via the tubing 216), the reservoir syringe 110, and the inflation syringe 10. The central member 122 has a cylindrical body 124 contained in a housing 126 of the valve, with the fittings 114, 116, 118 integrally formed on the housing. Apertures 128-130 are provided circumferentially about the body 124 at three locations. The aperture locations correspond to the lumens of the fittings 114, 116, 118. The body 124 protrudes out of an upper end of the housing 126 and terminates in a lever 132 for positioning by a clinician for the appropriate flow path. Preferably, the portion of the central member body 124 below the lever 132 does not have an aperture (e.g., there is no aperture in the vertical wall of the housing 126 which is aligned beneath the lever 132), such that the position of the lever 132 indicates which lumen is closed.

Thus, in the lever position of **Figure 5A**, with the inflation syringe 10 to the left, the reservoir syringe 110 toward the reader, and the tubing 216 to the right, the fluid path is through the lumens of the inflation syringe 10 and the guidewire 16. That is, the aperture 130 is aligned with the fitting 118 leading to the inflation syringe 10, and the aperture 128 is aligned with the fitting 114 leading to the guidewire tubing 216, such that fluid flow from

left to right is facilitated. It will be noted that the aperture 129, in this lever position of **Figure 5A**, is the back of the body 124 which is a closed position. This aperture is closed by means of the house 126, it being understood that **Figure 5A-5C** schematically represent the flow of fluid in the valve 112. Thus, the lever position of **Figure 5B** corresponds to flow between the inflation and reservoir syringes (e.g., the aperture 129 is in fluid communication with aperture 130 leading to the reservoir syringe 110, the aperture 130 not being visible in **Figure 5B** because of the partial cross-section), and the position of **Figure 5C** corresponds to flow between the reservoir syringe and guidewire lumens (e.g., aperture 128, which is not shown in **Figure 5C** due to the partial cross-section, leading from the reservoir syringe 110 is in fluid communication with aperture 129 leading to the guidewire tubing 216). It will be noted from **Figures 5B and 5C** that the lever 132 in each case is directed toward the device which is closed from fluid communication, e.g., the guidewire tubing 216 in the case of **Figure 5B** and the inflation syringe 10 in the case of **Figure 5C.**

An alternative syringe assembly is shown in **Figure 12**, wherein a conventional four-way manifold 200 is attached to the reservoir syringe 110 and a y-connection 210 attached to the proximal end of catheter 212. The manifold 200 provides a pressure monitoring line 202, a dye supply line 204, a saline supply line 206, and a waste removal line 208. Proximal this first connection 210, another y-connection 210 couples the low volume syringe 10 with the guidewire 16 and, thus, with the manifold 200 and reservoir syringe 110. the syringe 10 is used to inflate the distal balloon 14 on guidewire 16. Although the use of a manifold 200 is typically reserved for procedures using larger or therapeutic balloons, those skilled in the art will appreciate that the present invention is readily adapted for use with this more elaborate system.

As understood by those skilled in the art, the assembly in the present invention is not limited to the embodiments discussed herein, and may be included with other adapters, manifolds, and/or connectors, as desired. That is, advantages realized from the use of the low volume syringe with the higher volume syringe for deflation and inflation of a balloon during various procedures is not limited to their particular connections or additional apparatus.

Methods of Inflating a Medical Balloon

One method of inflating a medical balloon using an inflation syringe 10 having features of the present invention may be described with reference to **Figure 1.** The balloon catheter 12 may have already been primed or evacuated, and the balloon 14 may have already been inserted to its desired position within the patient, as desired. Alternatively, these steps may be performed after the syringe assembly 100 has been secured at the proximal end of the catheter 12. In addition, the inflation adapter 30 may be used to perform additional procedures requiring access to the inflation lumen 15 of the catheter, as known to those skilled in the art, prior to use of the syringe assembly 100 of the present invention, it being noted that the present method is not limited to the use of an inflation adapter 30 or the like.

In the present method, a proximal end of the balloon catheter 12 having a low profile valve 32 is arranged to lie within the inflation adapter 30 such that a side-access inflation port 17 of the catheter is located within a sealed inflation area contained in the adapter housing. The low profile valve 32 is closed (**Figure 3A**) and an

actuator 40 on the adapter 30 is in a first position, such that any flow through the inflation lumen 15 of the catheter 12 is prevented. Next, the adapter 30 is closed and secured using a locking clip 38.

It should be noted that more than one reservoir or high volume syringe 110 may be used, as necessary or desirable according to the procedure and/or clinician. That is, a first reservoir syringe may be used in the assembly 100 to prime the catheter's inflation lumen 15 and the balloon 14, with the valve lever 132 in the position of **Figure 5C** (the inflation syringe 10 to the left of the figure). The inflation syringe 10 may be pre-filled or empty, or, alternatively, a plug (not shown) may be temporarily used in place of the syringe 10. The lever 132 could then be positioned as in **Figure 5A** so that the first reservoir syringe can be removed and a second reservoir syringe containing dye or other inflation fluid can be connected to the valve 112.

The lever 132 is then positioned as in **Figure 5B** to allow the fluid to flow from the reservoir syringe 110, through the fitting 118 where the inflation syringe 10 has been attached, and into the inflation syringe 10, the intake of the syringe 10 being limited by its tube 70. The lever 132 is then positioned as in **Figure 5A** to allow injection of the pressurized fluid into the catheter 12.

If an inflation adapter 30 is being used, the actuator 40 is moved from the first position to a second position, thereby moving the panels 291 to cause the opening of the low profile valve 32 (**Figure 3B**) and to allow flow into the inflation port 17 of the catheter 12. Delivery of the inflation fluid is complete upon the depression or pushing of the syringe plunger 50. The actuator 40 is moved back to the first position to reposition the panels 291 and close the valve 32 to maintain the balloon 14 in its inflated state. The low volume syringe 10 may then be removed, and/or the necessary medical procedures continued. A third large capacity syringe 110 may be substituted at the fitting 116 with the lever 132 in the position of **Figure 5C** for quick deflation of the balloon 24 and removal of the catheter 12 from the patient.

An alternative method of inflating a low volume balloon utilizes the system shown in **Figure 12**, and is more typically used with larger balloons. The steps of this method are similar to those described for use of the three-way valve 112 wherein the various flow paths are achieved by use of the manifold 200. Additional steps, as desired or required, may be included for the removal of air/fluid waste, arterial pressure monitoring, and the injection(s) of dye and/or inflation fluid as accommodated by the lines 208, 202, 204, 206, respectively, of the manifold 200. In this method, however, the low volume syringe 10 is preferably filled, according to the limits of its stop member 20, prior to attachment to the y-connector 210.

Thus, the stop mechanism comprising either integral or retro-fit members of the present invention provides built-in control during the use of the syringe. The stop member can be provided for a predetermined intake displacement and also, preferably, for a predetermined fluid delivery displacement. The combination of the initial syringe capacity and the specific plunger displacement limits provided by the stop member determine the effective capacity of the low volume syringe. The elongate nature of the cylinder lumen preferably allows travel, for example, of about 10 mm by the piston in the lumen for the delivery of about 0.1 cc of fluid. This relatively large amount of travel for a small amount of fluid provides enhanced tactile feedback to the clinician that the fluid delivery was achieved.

High Pressure Capacity Syringe System

During the inflation of the occlusion balloon 14, the pressure in the system adjacent to the syringe 10 can reach pressures up to 200 psi. This pressure build up is caused by the sudden volume change caused by the influx of fluid into the valve 112 and lines 216 and 16 leading to the occlusion balloon 14. The build up pressure will peak initially and then dissipate as the pressure disperses through the lines 216, 16 toward the occlusion balloon 14. Eventually, the build up pressure will dissipate when the occlusion balloon 14 inflates. Typically, the build up pressure peaks and then stabilizes within 5 seconds. Therefore, the syringe system 100 must be able to withstand the peak pressure for at least 5 seconds.

Figure 13 illustrates a system that can withstand the initial build up pressure. The system is similar to the dual syringe system 100 of **Figures 1** and **4**. To avoid confusion, reference numerals of identical parts will remain the same whereas new parts will receive new numbers. Although this figure illustrates a dual syringe system, this by no means limits the invention to this configuration. For example, the high pressure capability syringe system can be incorporated in conjunction with a single syringe system.

In **Figure 13**, the large volume syringe 110 is attached and in fluid communication with a three-way high-pressure stop cock valve 322. A preferred provider of the high pressure valve is Merit Medical Systems part number M3SNP. Preferably, the valve is rated to handle pressures of 250 psi. Even more preferably, the valve 322 should be rated to withstand a pressure of 500 psi. Luer type couplings extend from all sides of the valve 322. Preferably the coupling 262 includes an extended engagement area, namely a greater number of threads, to ensure the positive sealing between the low volume syringe 10 and the valve 322. Likewise, the syringe 10 includes a mating, engagement area to complete the connection between the syringe 10 and the fitting 362. Although not illustrated, an O-ring could be incorporated between the mating surfaces of the syringe 10 and the fitting 362 to insure a leak-free seal.

A similar high pressure fitting 364 is located on the opposing side of the high pressure stop cock valve 322. As before, this fitting 364 has an extended engagement area, i.e. more threads, to lessen the load caused by the high build up pressure. Attached to the high pressure fitting 364 is a high pressure line 316 leading either to an inflation device or directly to the occlusion balloon (both not shown in this figure). Preferably, the high pressure line 316 is rated to withstand a pressure of 250 psi. Even more preferably, the line 316 is rated to withstand a pressure of 500 psi. An example of the line is part number 70078 manufactured by Mallinkrodt.

Still referring to **Figure 13**, a similar high pressure fitting 366 is located on the remaining side of the high pressure stop cock valve 322. As before, this fitting 366 preferably is a luer type connector with an extended engagement area, i.e. more threads, to lessen the load caused by the high build up pressure. Attached to the high pressure fitting 366 is a large volume reservoir syringe 110 which has a mating connector at a distal end which mates with the high pressure fitting 366 to insure a fluid tight seal.

Connectivity of the Valve

The connectivity of the valve 322 is the same as illustrated in **Figures 5A-5B**. The valve 322 can be set in a first position providing fluid communication between the low volume 10 syringe and the high volume syringe 110.

The valve 322 can also be set in a second position providing fluid communication between the low volume syringe 10 and the high pressure line 316. Finally, the valve 322 can be set in a third position in which fluid communication is provided between the high volume syringe 110 and the high pressure line 316.

Through the use of a high pressure valve 322 and a high pressure fittings 362, 364 and 366 leaks in the system are prevented. Further, even though the figure illustrates a dual syringe system with a three position valve, the high pressure system can be comprised of a single syringe system with or without a valve.

Removable Plunger Stop Mechanism

As previously discussed, the large volume syringe 110 can be used to create a vacuum. The vacuum is created by pulling the plunger 374 toward a proximal portion of the housing 370. In order to maintain the negative pressure the plunger 374 must be held in place. Typically, this is achieved by pulling the plunger 374 toward the proximal end of the housing 370 until the plate 376, mounted on the end of the plunger 374 is snapped into position proximal of a ring 372 extending radially inward into to the housing 370. The ring 372 holds the plunger 374 in place and maintains a vacuum within the system.

In order to prevent the complete withdrawal of the plunger 374 from the housing 370, a plunger stop mechanism 380 is incorporated with the high volume syringe 110. The plunger stop mechanism 380, in the embodiment shown in **Figure 13, Figure 14A** and **Figure 14B** is comprised of two removable clips 382. Preferably, the clips 382 are slid onto the finger stops 384 of the housing 370. Although not illustrated, the clips 382 include snap fit means to positively engage either the finger stops 384 or the cylinder housing 370.

The clips 382 are shown in detail in **Figures 14A** and **14B**. Preferably, the clips 382 are made of a polycarbonate or nylon material. The shape of the clip 382, as shown in side view in Figure 14B is a U-section with uneven surfaces 386, 388. As best seen in **Figure 14A** the shape of the surface 386 is arcuate in shape to mate with the outside of the cylindrical housing 370 distal of the finger tab 384.

The surface 388 extends into the chamber created by the housing 370 and is positioned proximal of the finger stop 384. The shape of the surface 388 must be designed not to interfere with the shaft 390 of the plunger 374. Nevertheless, the surface 388 must extend into the cylinder so as to abut the disk 376 of the plunger 374 when the distal end of the plunger 374 is pulled toward the proximal end of the housing 370. To assemble the stopper mechanism 380 the clinical technician would simply push the clip 382 onto the finger tab 384 thereby locking the clips 382 in place.

The clips 382 as shown in **Figure 13, Figure 14A** and **14B** are removable from the finger stops 384. In an alternative embodiment (not shown) the clips 382 could be formed integrally with the finger stops 384 of the syringe 110. In this embodiment, the plunger 374 would be inserted into the housing at an angle to clear the surface extending into the cylinder of the housing.

Yet another embodiment (also not illustrated) would include a system with one clip formed integrally with the cylinder housing and the other clip snapped onto the finger stop. This arrangement would allow for improved ease of assembly of the plunger into the syringe housing. For example, the clinical technician would remove the clip

from the finger stop, place the plunger within the syringe housing and then replace the clip onto the finger stop effectively locking the plunger within the housing.

Clips Aiding in the Vacuum Creation

As mentioned earlier, the clinical technicians use the syringes as a vacuum source for aspiration or removal of air bubbles in a preparation setting. In order to provide a vacuum the plunger 374 must be pulled toward the proximal end of the housing 370 thereby creating a vacuum within the system. To maintain the vacuum the plunger 374 must be held into place. As illustrated above, a ring 372 extending into the cylinder of the housing 370 of the syringe 110 is used to hold the plunger 374 in place.

The clips 382, however, could also be used to hold the plunger 374 in place. For instance, in the embodiment where the clips are removable, the plunger 374 could be locked in place by the clips 382. In this configuration, the plate 376 would be located proximal of the surface 388.

Alternative Uses for the Dual Syringe System

In addition to providing a highly responsive inflation system for an occlusion balloon the dual syringe system also has a variety of other uses. For instance, the system could be used to deliver precise amounts of therapeutic drugs or medicine to the patient. The system may also be used to irrigation or aspiration. Additionally, the system can be used to infuse whole blood as is described below.

Typically, whole blood is infused into patients with roller type pumps. One problem associated with this type of pump is that roller mechanisms apply a shear stress that often damages the blood cells with the crushing force of the rollers. The dual syringe system could overcome the problem of damaging the blood by providing a hydrostatic pressure that would provide pressure for the transfusion without causing the damaging forces on the cells. The blood cells, because of their circular shape, can withstand great hydrostatic pressure and therefore would not be damaged. Preferably, the large volume syringe will be used to infuse blood.

An inflation syringe constructed in accordance with the present invention is preferably used in an assembly further comprising a reservoir syringe and a three-way valve. This assembly is preferably coupled to an inflation adapter used to open and close a catheter valve at the proximal end of the catheter. In a preferred method of the present invention, the three-way valve and catheter valve are used to communicate the reservoir syringe with the inflation lumen of the catheter to prime the balloon catheter prior to insertion into the patient's vasculature. The valves are then appropriately set by the clinician to allow the inflation syringe to easily and precisely deliver the proper amount of fluid through the catheter's inflation lumen to the balloon. In one application, the inflation fluid injected by the syringe may be dye for a fluoroscopy procedure. The valves are further set and the reservoir syringe used to deflate the balloon for withdrawal from the patient.

A low volume syringe, and an assembly comprising the low volume syringe and a reservoir syringe, having features in accordance with the present invention are not limited to use with the inflation adapter or three-way valve as presented herein. Other arrangements or assemblies may include this combination of syringes of the present invention. Similarly, the method of the present invention may omit the use of an inflation adapter and/or three-way valve, etc., without loss of benefit from the present invention.

The embodiments of the apparatus and method as described above are provided merely to illustrate the present invention. Changes and modifications may be made from the embodiments presented herein by those skilled in the art without departure from the spirit and scope of the invention, as defined by the appended claims.

WHAT IS CLAIMED IS:

1. A syringe adapted for use in medical procedures requiring relatively accurate volumetric delivery of fluids, comprising:

an elongate housing having a predetermined cross-sectional dimension and a distal end and a proximal end; and

a plunger longitudinally slidable within said housing to effect intake and outflow of said fluids, said plunger having a distal end and a proximal end;

said housing being dimensioned such that said cross-sectional dimension has a relatively low profile, and said plunger being cooperatively dimensioned within said housing such that a relatively long distance of travel of said plunger within said housing will result in a relatively low volume of fluid intake or outflow, whereby the amount of fluid delivered in said medical procedure can be accurately controlled by tactile manipulation.

2. The syringe of Claim 1, wherein a distance of travel of said plunger within said housing of about 10 mm results in the delivery of about .1 cc fluid.

3. The syringe of Claim 1, wherein said maximum volume contained in said syringe is in the range of between 0.1 cc to 1 cc of fluid.

4. The syringe of Claim 3, wherein said maximum volume contained in said syringe is in the range of between 0.25 cc to 0.5 cc of fluid.

5. The syringe of Claim 4, wherein said maximum volume contained in said syringe is no more than 0.5 cc.

6. The syringe of Claim 1, wherein said maximum volume expelled by said syringe is between about 0.02 cc to 1.0 cc of fluid.

7. The syringe of Claim 6, wherein said maximum volume expelled by said syringe is about 0.3 cc.

8. The syringe of Claim 1, further comprising a stop mechanism on said syringe to control the intake of fluid into said housing.

9. A syringe adapted for use in medical procedures requiring relatively accurate volumetric delivery of fluids, comprising:

an elongate housing;

a plunger longitudinally slidable within said housing to effect fluid intake and outflow; and

a stop mechanism mounted on said plunger to limit the distance of travel of said plunger within said housing, thereby limiting the amount of fluid.

10. The syringe of Claim 9, wherein said stop mechanism is mounted on said plunger so as to be substantially located within said housing.

11. The syringe of Claim 9, wherein said stop mechanism is mounted on said plunger so as to be located substantially outside of said housing.

12. The syringe of Claim 9, wherein said stop mechanism comprises a separate piece that is retro-fit onto said syringe.

13. The syringe of Claim 9, wherein said stop mechanism is integrally formed on said syringe.

14. The syringe of Claim 9, wherein said stop mechanism comprises a member at least partially surrounding said plunger, said member providing interference with said housing so as to limit the distance of travel of said plunger.

15. The syringe of Claim 14, wherein said member comprises a tubing surrounding said plunger and having a predetermined length dimensioned to limit the distance of travel of said plunger, thereby controlling the intake of fluid into said housing.

16. The syringe of Claim 15, wherein said tubing interferes with the proximal end of said housing to provide said stop mechanism.

17. The syringe of Claim 9, further comprising a stop mechanism mounted at the proximal end of said housing for interfering with the distal portion of said plunger.

18. A syringe for simply and precisely inflating a surgical balloon attached at a distal portion of an elongated tube, said tube having a proximal control portion, a sealed distal end and an inflation lumen extending therebetween for communicating fluid to said balloon, said syringe comprising:

an elongated cylinder having a proximal end and a distal end and a lumen extending therebetween, a flange formed at said proximal end and extending radially away from said lumen, said distal end adapted for attachment to said proximal portion of said tube;

a plunger for use in said cylinder and having a shaft with a disk provided at a proximal end and a sealing piston provided at a distal end of said shaft, said plunger inserted into said lumen of said cylinder such that said disk is positioned proximal said flange; and

a stop means provided at said proximal end of said cylinder for limiting the intake of said syringe, at least a portion of said stop means providing a channel for said shaft of said plunger to extend therethrough, said stop means having a first segment positioned distal of said flange of said cylinder and a second segment positioned proximal of said flange;

whereby said stop means limits the travel of said plunger within said cylinder, thereby limiting a maximum volume of fluid that can be drawn into said syringe and limiting a maximum volume of fluid that can be injected by said syringe.

19. A syringe for precisely inflating a balloon catheter for vessel occlusion, said catheter having a surgical balloon attached at a distal functional end of a guidewire, said guidewire having a longitudinally extending inflation lumen for conducting fluid to and from said balloon, said syringe comprising:

an elongated cylinder forming a lumen and having a proximal end and a distal end, a finger stop formed about said proximal end and extending outwardly from said lumen, said distal end adapted to attach to a proximal portion of said catheter;

a plunger for use in said cylinder and having a shaft with a disk provided at a proximal end and a piston provided at a distal end of said shaft, said disk having a diameter larger than a diameter of said shaft, said piston having a diameter substantially the same as a diameter of said lumen of said cylinder;

a barrel provided proximal said finger stop at said proximal end of said cylinder, said barrel having a length and a longitudinal channel formed therethrough, said channel having a diameter sized to receive said shaft of said plunger; and

a tube provided at a proximal end of said lumen, said tube having an outer diameter less than said diameter of said lumen and an inner diameter forming a longitudinal channel, said inner diameter sized to receive said shaft of said plunger;

wherein said tube has a length for limiting the proximal travel of said plunger and thereby limiting a maximum volume of fluid that can be contained in said syringe, said barrel having a length for limiting the distal travel of said plunger and thereby limiting a maximum volume of fluid that can be expelled from said syringe.

20. A syringe assembly adapted for use in delivering fluids during a medical procedure, comprising:

a first syringe;

a second syringe; and

a fluid conduit for delivering said fluid during said medical procedure;

said first syringe being in fluid communication with said second syringe or said fluid conduit, and said second syringe being in fluid communication with said first syringe or said fluid conduit.

21. The syringe assembly of Claim 20, further comprising a valve for achieving fluid communication among said first syringe, said second syringe, and said fluid conduit.

22. A syringe assembly for use with a low volume surgical balloon attached at a distal portion of an elongated tube, said tube having a proximal portion, a sealed distal end and an inflation lumen extending therebetween for communicating fluid to said balloon, said assembly comprising:

a connector having two upstream ports, one downstream port and a flow deflector, said downstream port configured for attachment to said proximal portion of said tube;

a low volume syringe having an elongated body and a stop member, said syringe limited to delivery of a relatively small volume of fluid, one of said upstream ports attached to a distal end of said low volume syringe; and

a large volume syringe having a relatively large fluid capacity, a distal end of said reservoir syringe adapted to attach to the other of said upstream ports;

wherein said large volume reservoir syringe is configured to facilitate quick evacuation of said inflation lumen and said balloon, said large volume syringe providing fluid to said low volume syringe as required.

23. A method of precisely inflating an occlusion balloon inserted and positioned at a desired segment within a blood vessel of a patient using a guidewire, said guidewire comprising an elongated tube having a proximal end, a distal end, and a longitudinally extending lumen extending therebetween for communication with said balloon, said method comprising the steps of:

a) providing a syringe having a cylindrical body with a plunger inserted through a lumen of said body, said syringe having a stop member provided at a proximal end;

b) providing a source of inflation fluid for said balloon;

c) attaching a distal end of said syringe to said source of inflation fluid;

d) pulling on a proximal end of said plunger until travel of said plunger is stopped by said stop member, said syringe filled with a small amount of said inflation fluid;

e) attaching said distal end of said syringe to said guidewire so that said lumen of said syringe is in communication with said lumen of said guidewire; and

f) pushing on said proximal end of said plunger until travel of said plunger is stopped by said stop member;

whereby said syringe delivers a predetermined amount of fluid as defined by said stop member.

24. The method of Claim 25, wherein said predetermined amount of fluid is between about 0.02 and 1.0 cc.

25. The method of Claim 25, further comprising attaching an injection cap to said distal end of said syringe prior to attachment of said syringe to said guidewire for inflation of said balloon.

26. A method of easily and precisely inflating a low volume balloon catheter comprising an elongated tube having a proximal portion and a sealed distal end with a surgical balloon attached thereto, said tube having a longitudinally extending lumen communicating with said balloon for inflation thereof, said method comprising the steps of:

a) inserting and positioning said tube and balloon at a desired position within a blood vessel of a patient;

b) providing a three-way valve having first and second inlet ports and an outlet port, said outlet port adapted to be attached to said proximal portion of said tube;

c) providing a low volume syringe adapted to be attached to said first inlet port of said valve, said low volume syringe having an inflation lumen and a stop member for limiting injection of inflation fluid to a predetermined amount;

d) providing a high volume syringe adapted to be attached to said second inlet port of said valve, said high volume syringe having a reservoir lumen;

e) positioning said valve to communicate said high volume syringe with said lumen of said tube and pulling on a plunger of said high volume syringe to effect evacuation of air or fluid within said tube, said balloon and said outlet port of said connector into said high volume syringe;

f) positioning said valve so that said inflation lumen of said low volume syringe communicates with said lumen of said tube; and

g) pushing said plunger of said low volume syringe to deliver said predetermined amount of fluid to said tube and said balloon;

whereby said predetermined amount of fluid inflates said balloon to an appropriate size without rupture of said balloon or damage to said blood vessel of said patient.

27. The method of Claim 26, wherein step e) is performed to evacuate or prime said balloon catheter.

28. The method of Claim 26, wherein step e) is performed to deflate said balloon prior to its removal from a patient.

29. A method of easily and precisely inflating a low volume balloon on a catheter, the catheter comprising an elongated tube having a proximal portion and a sealed distal end with a balloon attached thereto, said tube having a longitudinally extending lumen communicating with said balloon for inflation thereof, said method comprising the steps of:

a) providing a three-way valve having first and second inlet ports and an outlet port;

b) providing an inflation adapter assembly attached to said outlet port of said three-way valve and attached to said proximal portion of said tube selectively positioned in a first position to allow fluid communication through said inflation adapter and a second position to prevent fluid communication to said inflation adapter;

c) providing a low volume syringe adapted to be attached to said first inlet port of said valve, said low volume syringe having an inflation lumen and a stop member for limiting injection of inflation fluid to a predetermined amount;

d) providing a high volume syringe adapted to be attached to said second inlet port of said valve, said high volume syringe having a reservoir lumen;

e) positioning said inflation adapter in a first position to allow fluid communication through said inflation adapter and to said tube;

f) positioning said valve to communicate said high volume syringe with said lumen of said tube and pulling on a plunger of said high volume syringe to effect evacuation of air or fluid within said tube, said balloon and said outlet port of said connector into said high volume syringe;

g) inserting and positioning said tube and balloon at a desired position within a blood vessel of a patient;

h) positioning said valve so that said inflation lumen of said low volume syringe communicates with said lumen of said tube;

i) positioning said inflation adapter in a first position to allow fluid communication through said inflation adapter and to said tube;

j) pushing said plunger of said low volume syringe to deliver said predetermined amount of fluid to said tube and said balloon; and

k) positioning said inflation adapter in a second position to prevent fluid communication through said inflation adapter and to said tube;

whereby said predetermined amount of fluid inflates said balloon to an appropriate size without rupture of said balloon or damage to said blood vessel of said patient.

30. A syringe assembly adapted for use in delivering fluids during a medical procedure, comprising:

a low volume syringe;

a large volume syringe;

a high pressure valve assembly; and a

a high pressure fluid conduit;

wherein said high pressure valve assembly is in fluid communication with said low volume syringe, said large volume syringe and said high pressure line and said high pressure valve selectively allows fluid communication between;

a) said large volume syringe and said low volume syringe, or;

b) said low volume syringe and said high pressure fluid conduit, or;

c) said large volume syringe and said high pressure fluid conduit.

31. A syringe assembly of Claim 30 wherein the maximum volume contained in said low volume syringe is in the range of between 0.1 cc to 1 cc of fluid.

32. A syringe assembly of Claim 30 wherein the maximum volume contained in said low volume syringe is in the range of between 0.25 cc to 0.5 cc of fluid.

33. A syringe assembly of Claim 30 wherein the maximum volume contained in said large volume syringe is in the range of between 10 cc to 30 cc.

34. A syringe assembly of Claim 30 wherein said high pressure line is rated for use at a pressure of 500 psi.

35. A syringe assembly of Claim 30 wherein said high pressure line is rated for use at a pressure of 250 psi.

36. A syringe assembly of Claim 30 wherein said high pressure valve is rated for use at a pressure of 750 psi.

37. A syringe assembly of Claim 30 wherein said high pressure valve is rated for use at a pressure of 500 psi.

38. A syringe assembly of Claim 30 further including a plunger stopper element positioned on a proximal end of said large volume syringe to prevent the withdrawal of a plunger reciprocating within a cylinder defining a lumen of said large volume syringe.

39. A syringe assembly of Claim 38 wherein said plunger stopper element is integrally molded into a proximal end of said large volume syringe.

40. A syringe assembly of Claim 38 wherein said syringe stopper element includes at least two snap fit members removably attached to a proximal end said large volume syringe.

41. A syringe assembly adapted for use in delivering fluids during a medical procedure, comprising:

a low volume syringe;

a large volume syringe;

a high pressure valve assembly;

a high pressure fluid conduit; and a

a stopper means attached to said large volume syringe for preventing the withdrawal of a plunger reciprocating therein;

wherein said high pressure valve assembly is in fluid communication with said low volume syringe, said large volume syringe and said high pressure line and said high pressure valve selectively allows fluid communication between;

a) said large volume syringe and said low volume syringe, or;

b) said low volume syringe and said high pressure fluid conduit, or;

c) said large volume syringe and said high pressure fluid conduit.

42. A syringe assembly of Claim 41 wherein the maximum volume contained in said low volume syringe is in the range of between 0.1 cc to 1 cc of fluid.

43. A syringe assembly of Claim 41 wherein the maximum volume contained in said low volume syringe is in the range of between 0.25 cc to 0.5 cc of fluid.

44. A syringe assembly of Claim 41 wherein the maximum volume contained in said large volume syringe is in the range of between 10 cc to 30 cc.

45. A syringe assembly of Claim 41 wherein said high pressure line is rated for use at a pressure of 500 psi.

46. A syringe assembly of Claim 41 wherein said high pressure line is rated for use at a pressure of 250 psi.

47. A syringe assembly of Claim 41 wherein said high pressure valve is rated for use at a pressure of 750 psi.

48. A syringe assembly of Claim 41 wherein said high pressure valve is rated for use at a pressure of 500 psi.

49. A syringe assembly of Claim 41 wherein said stopper means is integrally molded into a proximal end of said large volume syringe.

50. A syringe assembly of Claim 41 wherein said stopper means includes at least two snap fit members removably attached to a proximal end said large volume syringe.

51. A syringe adapted for use in medical procedures requiring relatively accurate volumetric delivery of fluids, and capable of withstanding relatively high pressures comprising,

an elongate housing including a proximal and distal end;

a plunger longitudinally slidable within said housing to effect fluid intake and outflow and

a coupling for connection to a medical device rated to withstand a pressure of 500 psi.

52. A syringe of Claim 51 rated to withstand a pressure of 250 psi.

53. A plunger stop mechanism for a syringe including an elongate housing having a predetermined cross-sectional dimension, a distal end and a proximal end, a pair of finger stops extending radially outward from the center of said housing located on a proximal end of said housing, a plunger longitudinally slidable within said housing to effect intake and outflow of said fluids, said plunger including a disk mounted obliquely to a distal end of said plunger, said stop mechanism comprising:

at least one stop member removably attached to said finger stop of said elongate housing said stop member including a stop tab wherein said tab extends radially inward thereby at least partially closing said distal end of said housing.

54. A plunger stop mechanism of Claim 53 wherein said stop member is integrally formed with said finger stop.

55. A method of easily and precisely delivering fluids during a medical procedure comprising an elongated tube having a proximal portion and a distal end, said tube having a longitudinally extending lumen communicating with said distal end, said method comprising the steps of:

a) inserting and positioning said tube at a desired position within a blood vessel of a patient;

b) providing a three-way valve having first and second inlet ports and an outlet port, said outlet port adapted to be attached to said proximal portion of said tube;

c) providing a low volume syringe adapted to be attached to said first inlet port of said valve, said low volume syringe having an inflation lumen and a stop member for limiting injection of inflation fluid to a predetermined amount;

d) providing a high volume syringe adapted to be attached to said second inlet port of said valve, said high volume syringe having a reservoir lumen;

e) positioning said valve to communicate said high volume syringe with said lumen of said tube and pulling on a plunger of said high volume syringe to effect evacuation of air or fluid within said tube, said balloon and said outlet port of said connector into said high volume syringe;

f) positioning said valve so that said inflation lumen of said low volume syringe communicates with said lumen of said tube; and

g) pushing said plunger of said low volume syringe to deliver said predetermined amount of fluid to said tube and said balloon;

whereby said predetermined amount of fluid is delivered to said blood vessel without damage to said blood vessel of said patient.

56. The method of Claim 55 wherein said fluid to be delivered is irrigation fluid.

57. The method of Claim 55 wherein said fluid to be delivered is whole blood.

58. The method of Claim 55 wherein said fluid to be delivered is a therapeutic drug.

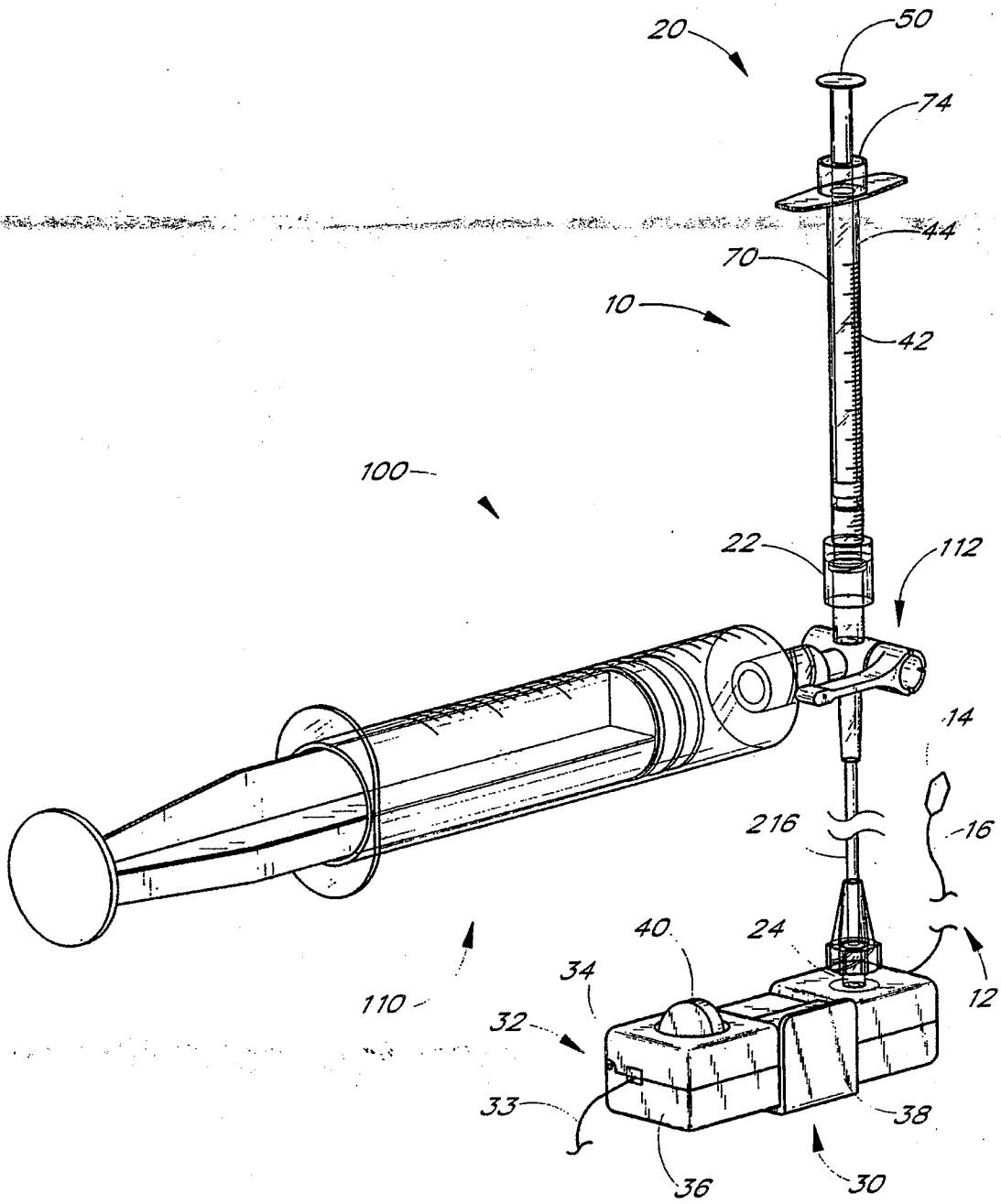
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FIG. 1

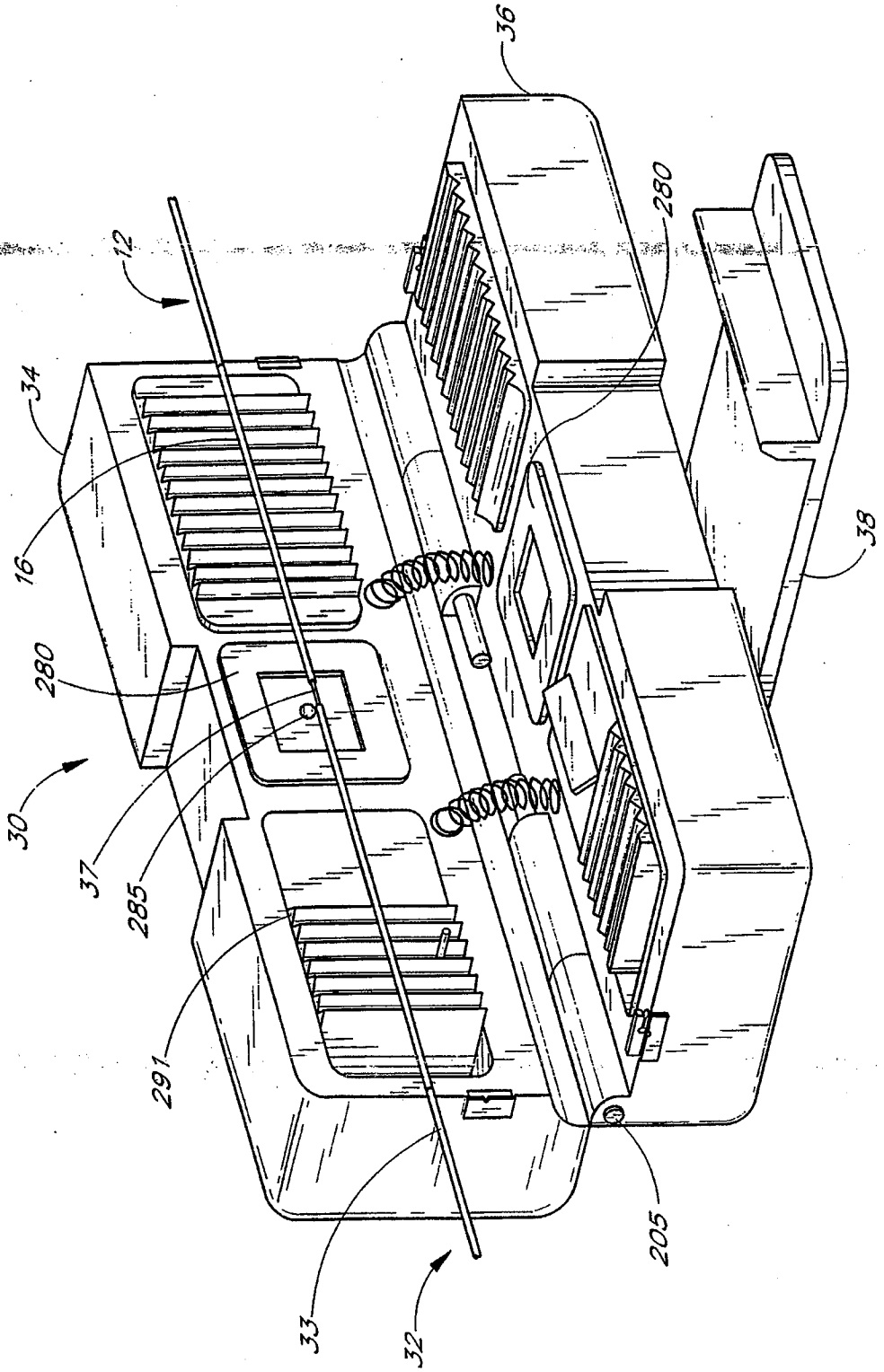

FIG. 2

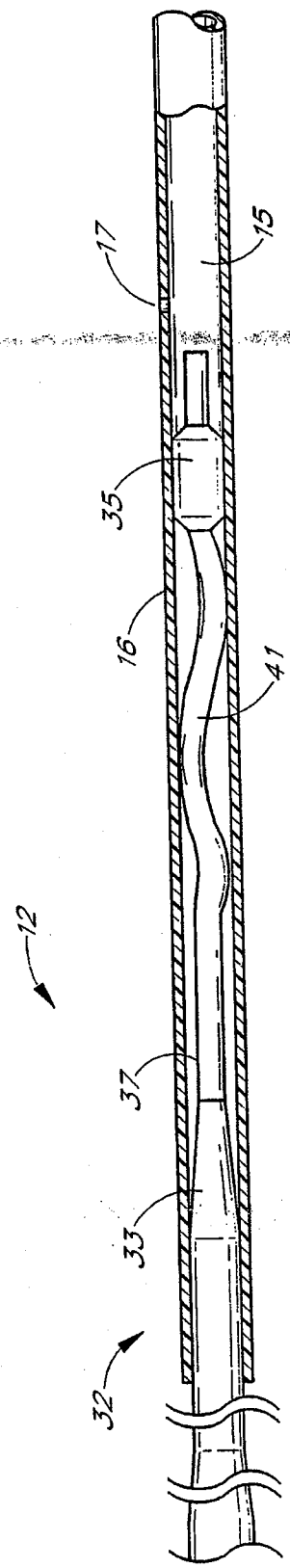

FIG. 3A

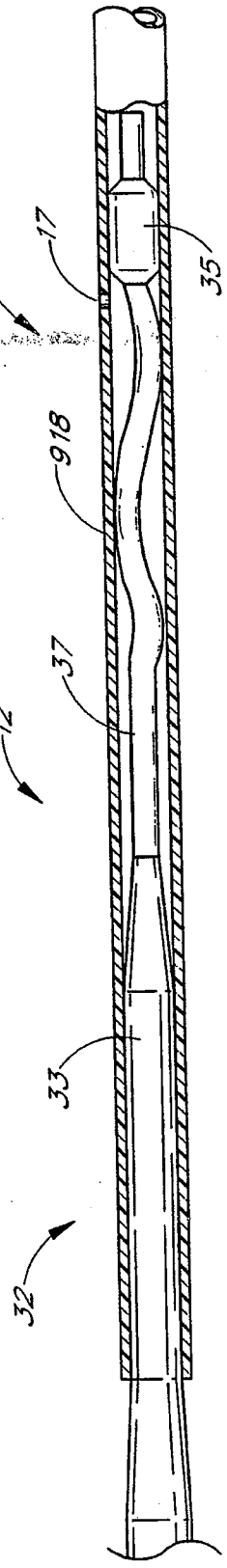

FIG. 3B

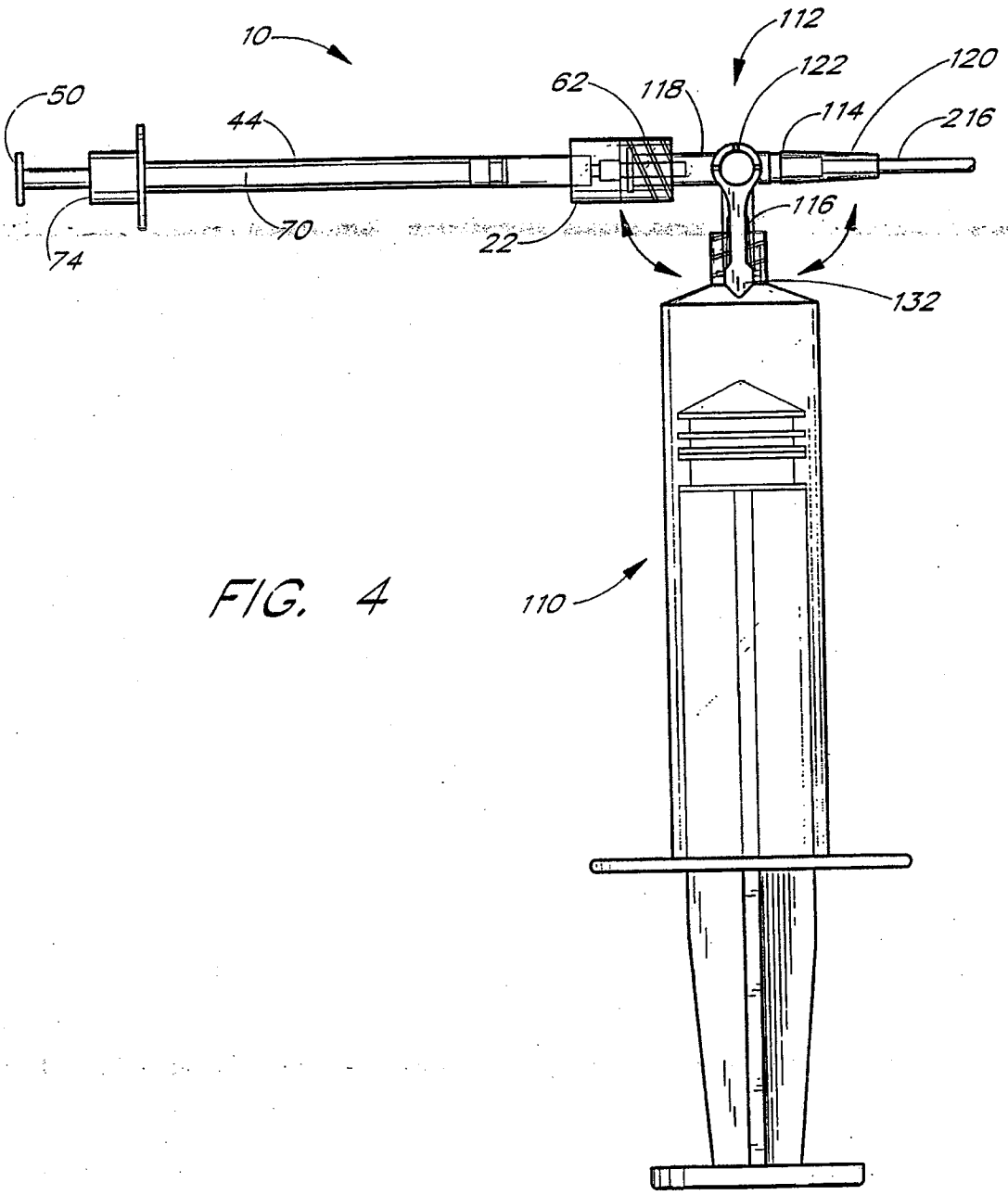

FIG. 4

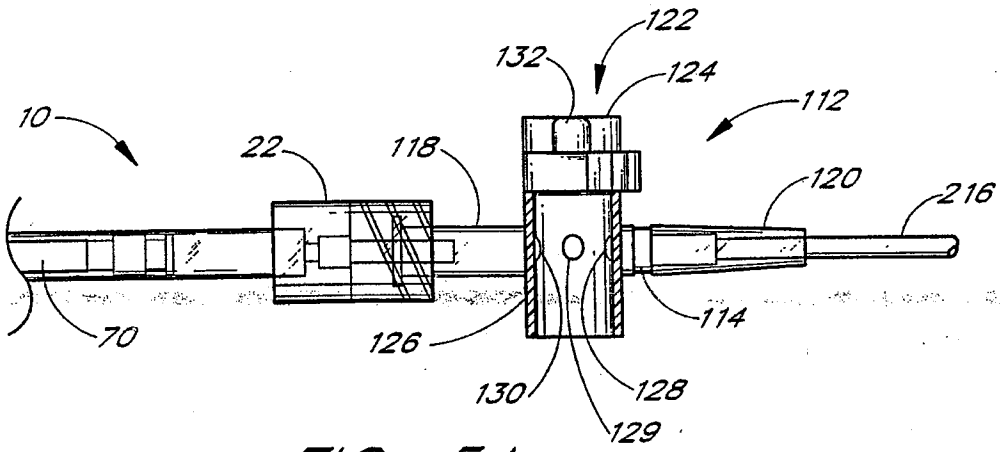

FIG. 5A

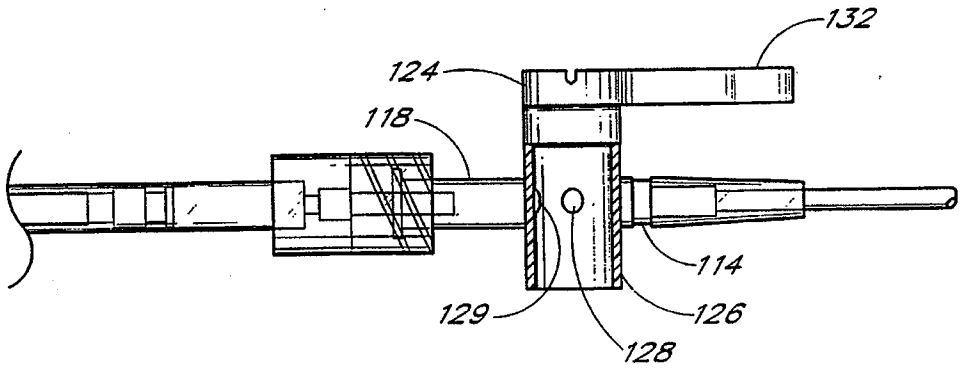

FIG. 5B

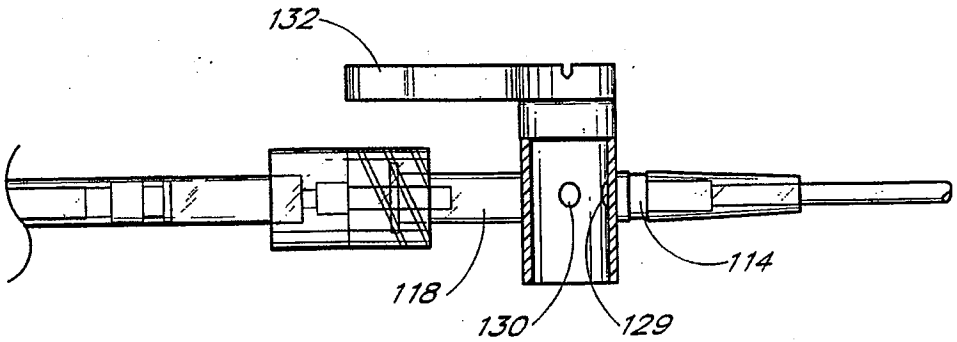

FIG. 5C

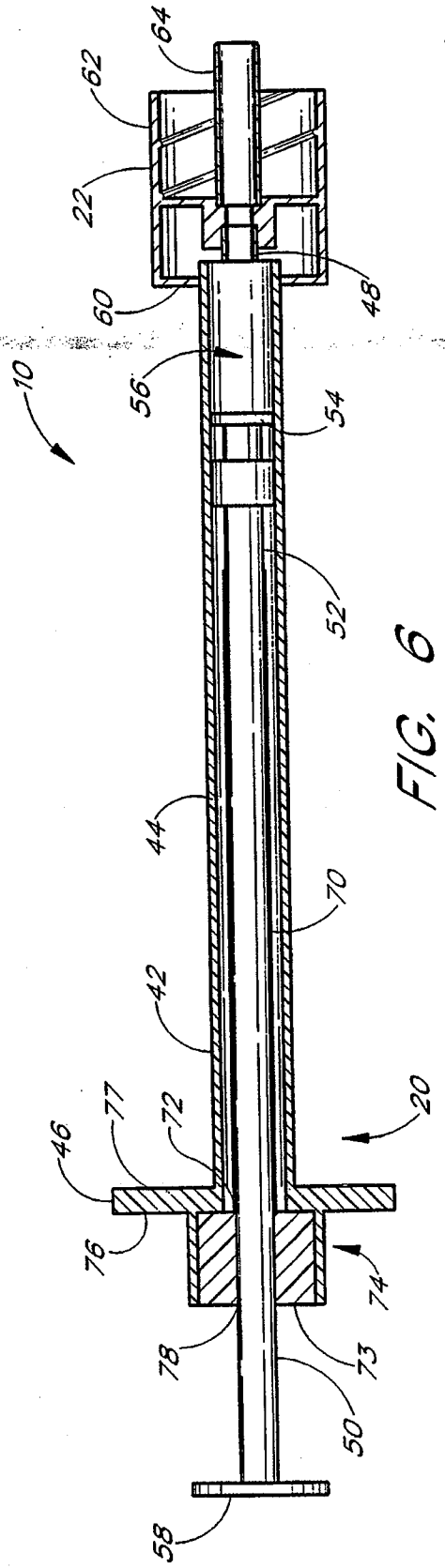

FIG. 6

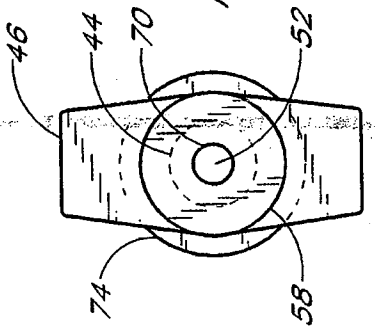

FIG. 7

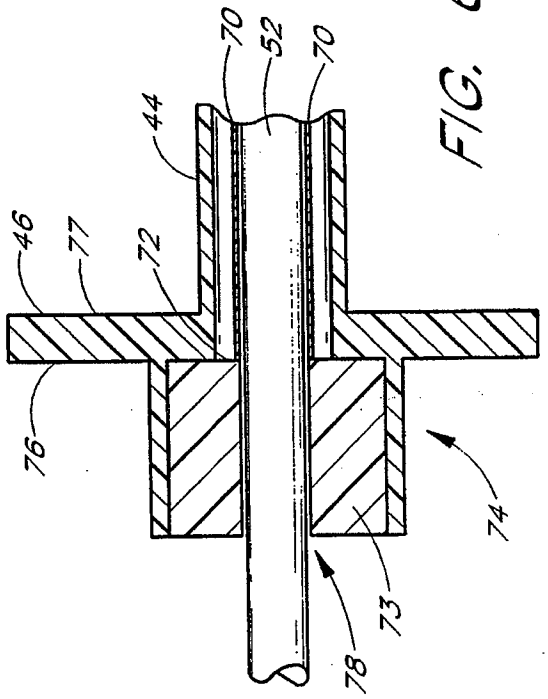

FIG. 6A

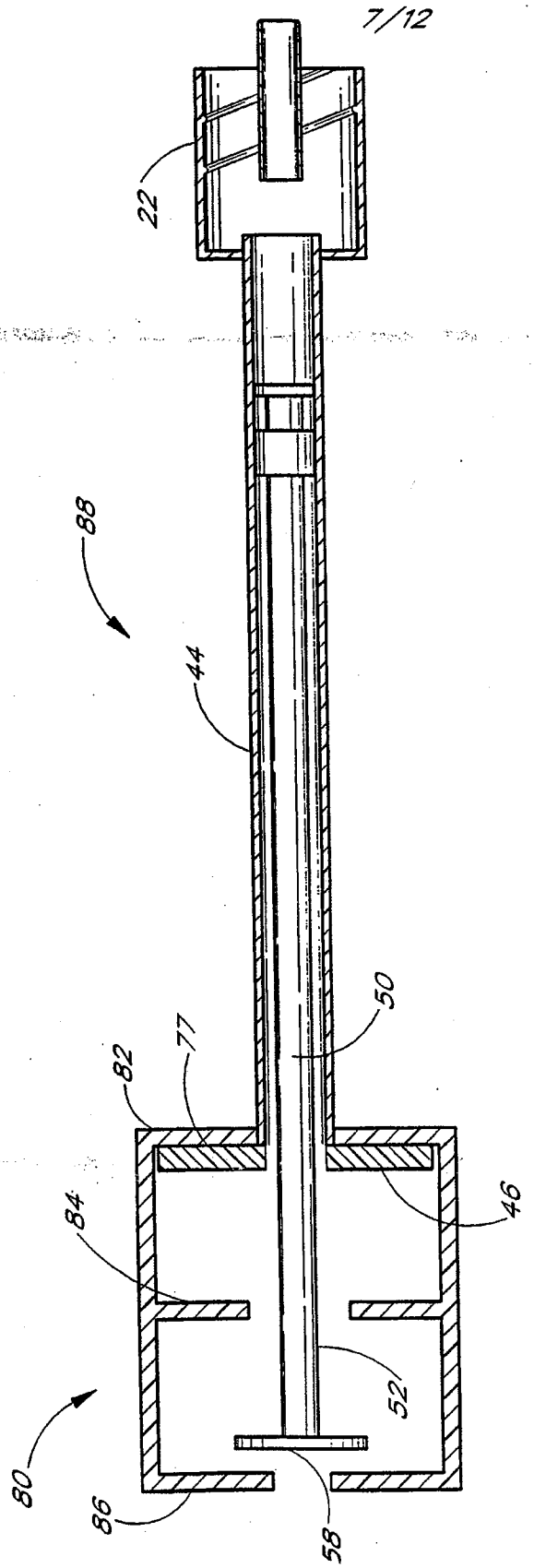

FIG. 8

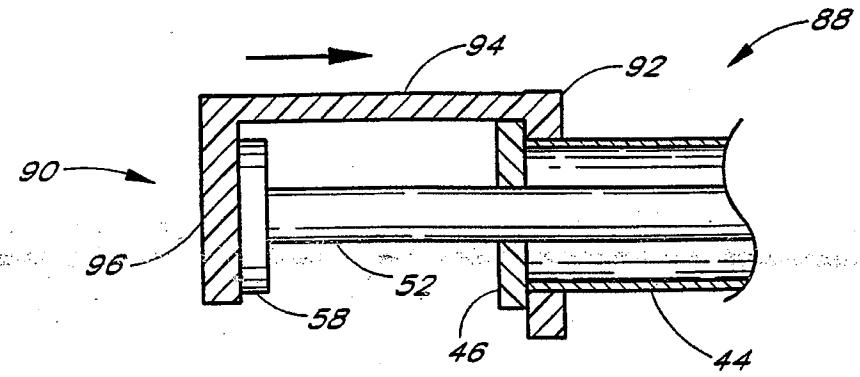

FIG. 9A

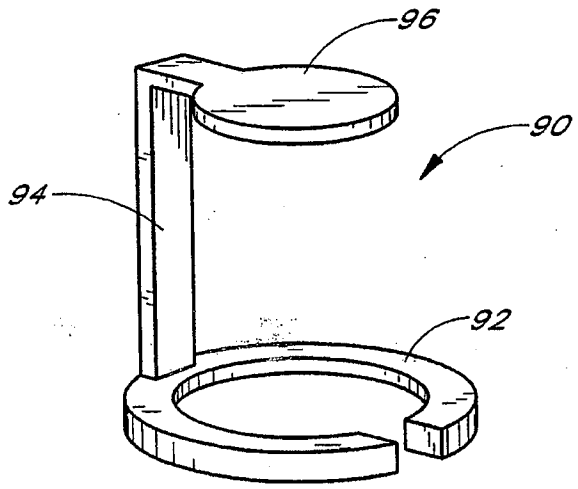

FIG. 9B

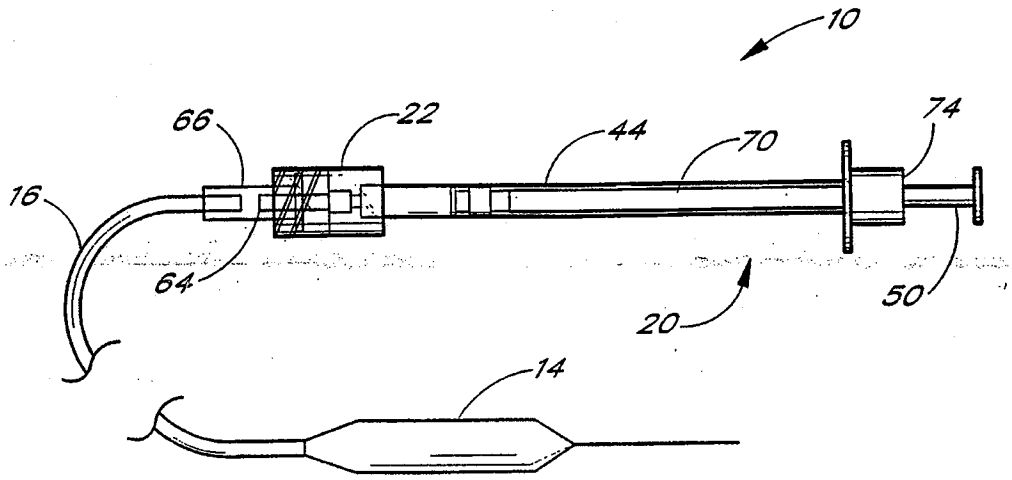

FIG. 10

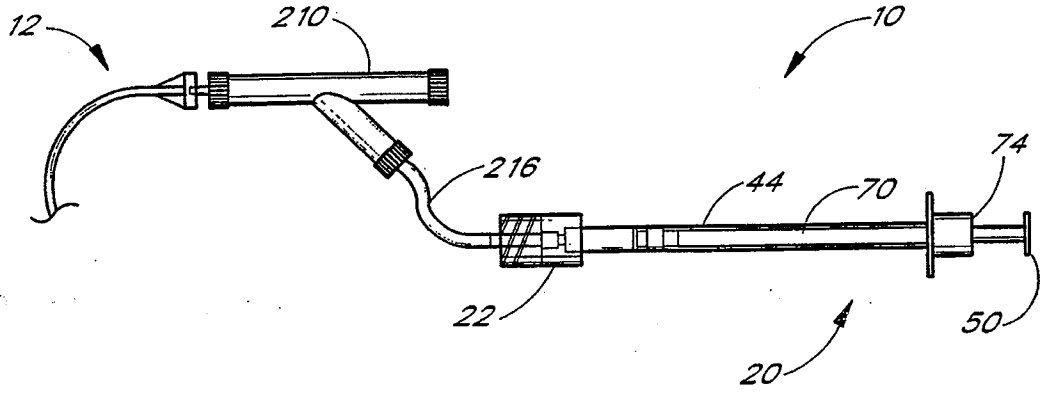

FIG. 11

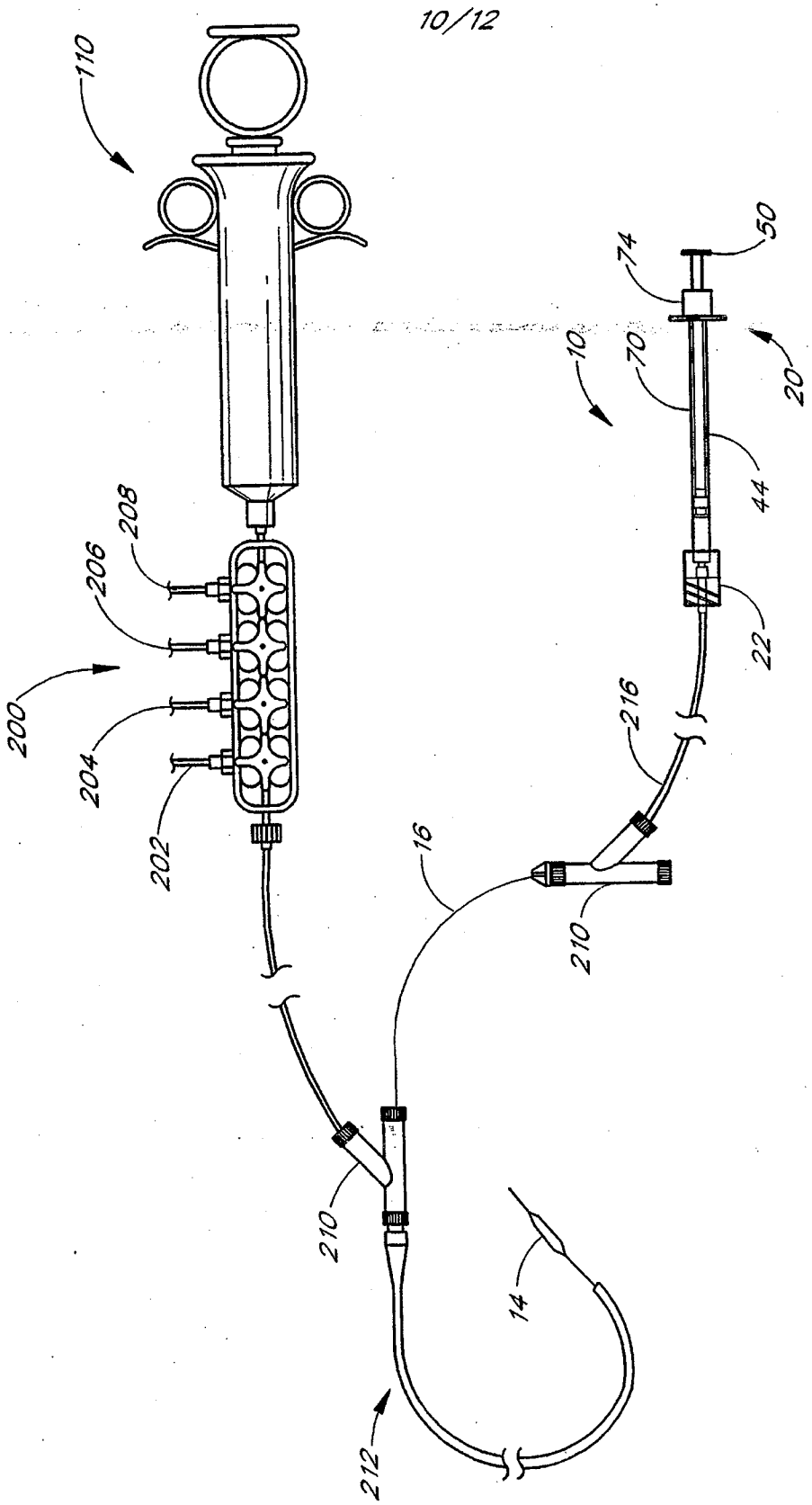

FIG. 12

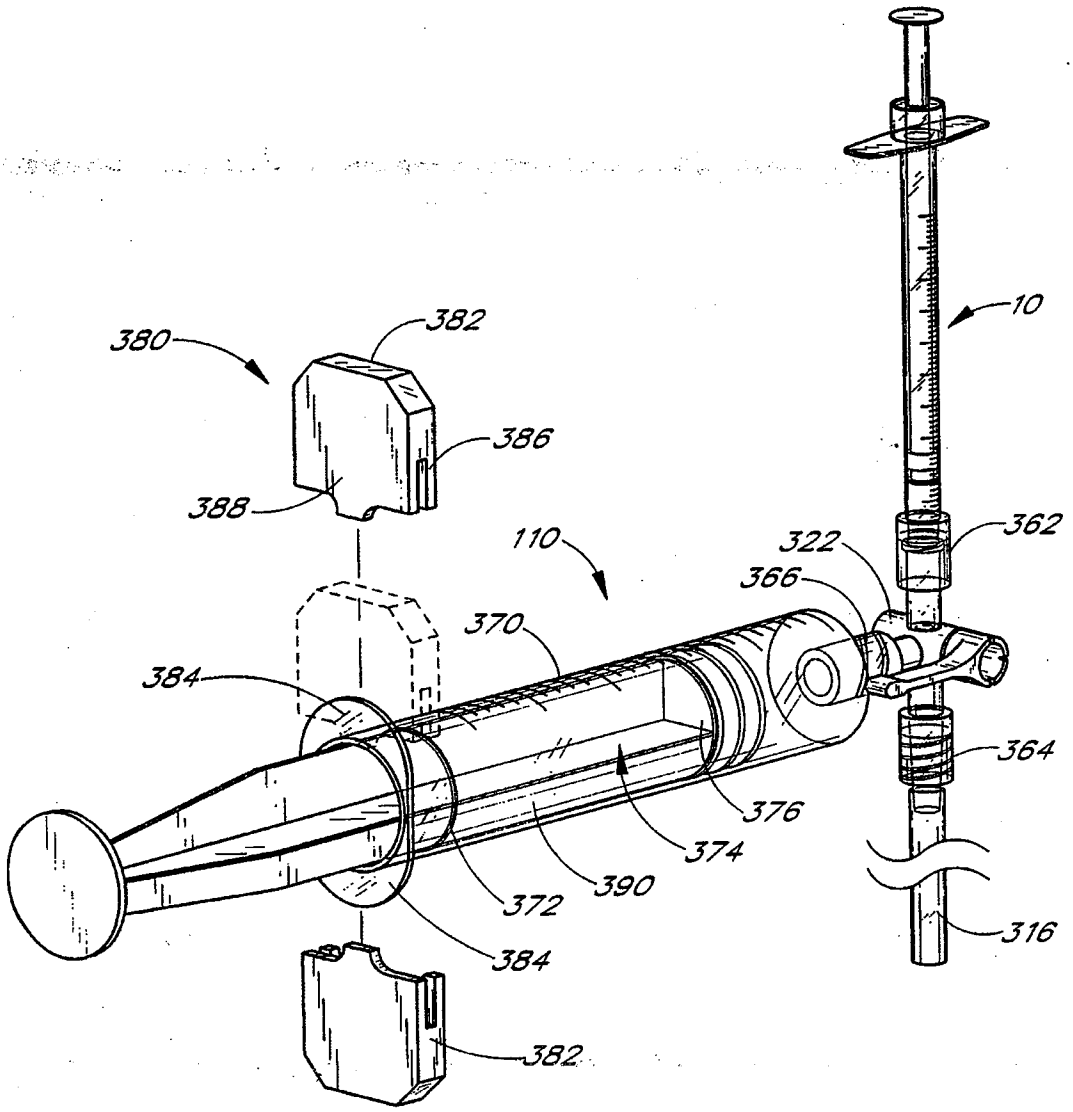
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FIG. 13

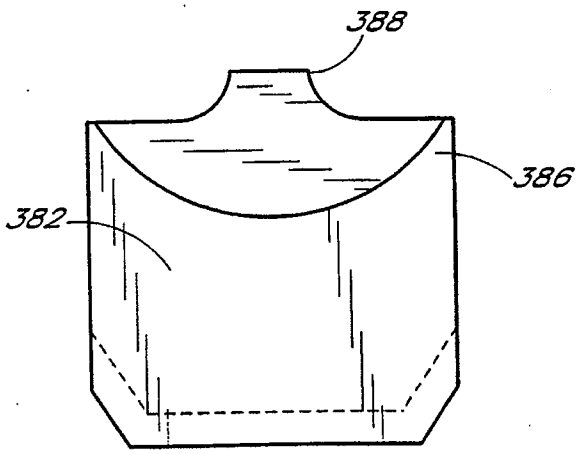

FIG. 14a

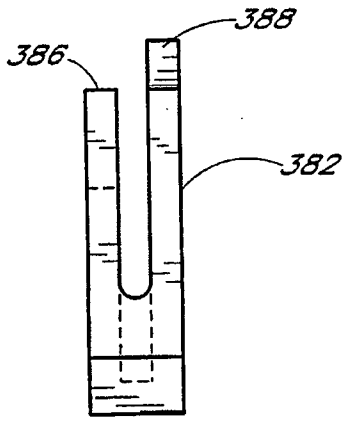

FIG. 14b

INTERNATIONAL SEARCH REPORT

Intern ial Application No
PCT/US 98/12257

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M5/315 A61M1/00 A61M5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 946 441 A (LADEROUTE MAURICE) 7 August 1990 see column 6, line 13 - line 24 see column 7, line 17 - line 29 see column 9, line 57 - line 59 see claims 1,2,5; figures 1,5	1,2, 8-10,14
Y		3-6, 11-13, 17,22
A		7

X	US 5 582 595 A (HABER TERRY M ET AL) 10 December 1996 see column 3, line 6 - line 13; figures 1,2	1,8
Y		13,54
A		39

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publicationdate of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of theinternational search	Date of mailing of the international search report
1 October 1998	09. 10. 98

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Sedy, R

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Interr ial Application No
PCT/US 98/12257

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 308 341 A (CHANOCH) 3 May 1994 see column 5, line 61 - line 65	3-6,31, 32
A		42,43
Y	US 2 860 635 A (WILBURN) 18 November 1958 see figures 7-11	11
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Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Intern ial Application No
PCT/US 98/12257

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 592 746 A (BURKHOLDER ET AL.) 3 June 1986 see abstract; figures	40,50
A	US 4 024 865 A (HAMILTON COMPANY) 24 May 1977 see column 1, line 8 - line 13	45-52

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/12257

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 23-29, 55-58
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [X] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-22,51-54

   syringe comprising plunger stopper means

2. Claims: 30-50

   syringe assembly comprising a low and a high volume syringes, high pressure valve and a high pressure fluid conduit

INTERNATIONAL SEARCH REPORT

...ormation on patent family members

Inter nal Application No
PCT/US 98/12257

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